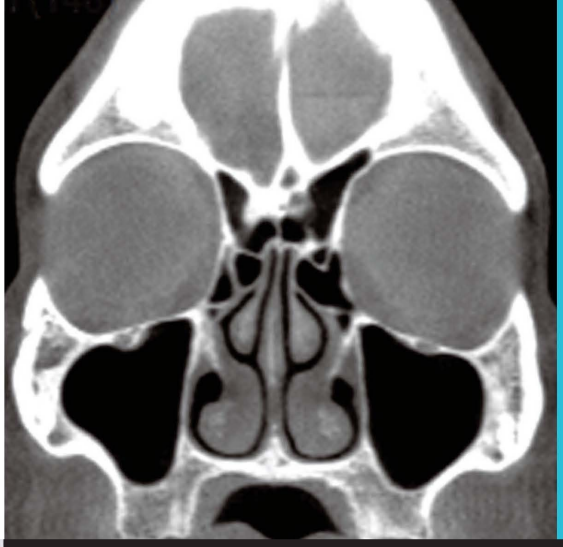

MiniCAT™

USER GUIDE

XORAN TECHNOLOGIES

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1.0 READ THIS FIRST

This section contains important safety information about using your MiniCAT™.

1.1 Radiation Guidelines

MiniCAT™ is an X-ray emitting device.

Warning: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed. Unauthorized use is prohibited.

- It is the responsibility of the user to learn about X-ray radiation health risks and to adopt and follow proper X-ray radiation safety policies and procedures before operating the MiniCAT™.
- All government and local regulations pertaining to radiation safety must be observed.
- Please refer to your local state radiation safety regulations for specific requirements about the safe and proper use of the scanner.
- Stand behind the operator's barrier when using X-ray.
- Lead-shielded aprons and dose monitoring badges may be required.

Note: The best practice is to consult with a qualified medical physicist to ensure safety and compliance. Feel free to contact Xoran for assistance in locating an appropriate medical physics professional in your area. 1-800-70-XORAN (800-709-6726)

1.2 Detailed Safety Instructions

Emergency Stop:

This manual contains instructions for safe operation of this X-ray system. In the event of an emergency (i.e. any moving component collides with any parts of the equipment or items in the environment, or that could cause physical injury to the patient), the operator should utilize the **EMERGENCY STOP (E-Stop)** button to turn off the power to all moving parts in order for the patient to be safely removed from the machine.

Patient E-Stop **Operator E-Stop**

X-Ray Warning System:

The MiniCAT™ has a flashing light (yellow) and makes an audible sound when the X-ray is firing. In addition it is possible to install external warning lights and/or audible alarms when X-ray is enabled in ready state. Call Xoran to learn more about these options if required in your area.

Door Interlock System:

The MiniCAT™ is equipped with provisions for an optional door interlock circuit. This type of circuit shuts off power to the X-ray source when the door is opened. Call Xoran to learn more about these options if required in your area.

Disposal:

Follow local regulations on disposal of waste parts. The X-ray source assembly, image sensor and all electronic circuits should be regarded as non-environmental friendly waste product.

Extension Cords / Cables:

Do not use any extension cords which have not been provided with the MiniCAT™. Use only the interface cables provided with the MiniCAT™. Do not alter the cabling configuration. (See section 2.6 Connectivity Diagram)

Additional Software and Accessories:

Do not connect any items or equipment to the MiniCAT™ which are not part of the system. Do not install any additional software on the system. Either of these actions can cause the system to malfunction and will result in voiding your warranty.

1.3 Table of Symbols

The following symbols can be found in this manual and on the equipment. They are described below.

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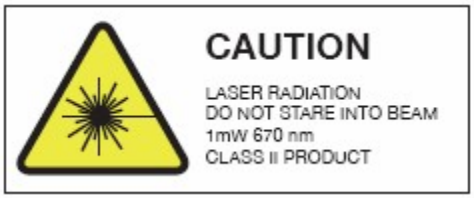
Symbol	Description
	Type B Applied Part
	Electric Shock, High Voltage: This symbol, wherever it appears, alerts you to the presence of uninsulated dangerous voltage inside the enclosure -- voltage that may be sufficient to constitute a risk of shock.
	Protective Earth, Ground: Grounding reliability can only be achieved with the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade."
	Attention: Consult accompanying documents.
	X-ray Caution: These symbols indicate the presence of X-radiation. This X-ray device may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.

Symbol	Description
	Pinch Point: This symbol alerts you to the potential for injury due to moving mechanical parts. Keep hands clear during operation.
	X-Ray Focal Spot: This symbol appears on the X-ray tube head, showing the approximate location of the X-ray focal spot.
	**Class II Laser:** This symbol alerts you to the presence of Class II laser light. Do not stare into the beam.

1.4 Electromagnetic Interferance

The MiniCAT™ has been tested and found to comply with the limits for Class B equipment, pursuant to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a commercial environment. The MiniCAT™ generates, uses and can radiate electromagnetic energy. If MiniCAT™ is not installed and used in accordance with these instructions, it may cause harmful interference to surrounding equipment.

MiniCAT™ is intended for use in an electromagnetic environment specified below. The customer or user of the MiniCAT™ should ensure that it is used in such an environment.

Immunity / Test	Electrostatic Environment- Guidance
Electrostatic Discharge	Compliant to +4 kV. Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT and Surge	Electrical power quality should be that of a typical commercial or

<table>
<tr><th>Immunity / Test</th><th>Electrostatic Environment- Guidance</th></tr>
<tr><td></td><td>hospital environment.</td></tr>
<tr><td>Voltage Dips/Dropout</td><td>Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply (included).</td></tr>
<tr><td>Conducted RF</td><td>Portable and mobile communication equipment should be separated from the MiniCAT™ by no less than 19 feet (6 meters).</td></tr>
<tr><td>Radiated RF</td><td>The MiniCAT™ is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the MiniCAT™ as recommended below, according to the maximum output power of the communications equipment.
<table>
<tr><th>Maximum Output Power

(Watts)</th><th>Separation

(150 kHz to 800 MHz)</th><th>Separation

(800 MHz to 2.5 GHz)</th></tr>
<tr><td>0.01</td><td>15 in (38 cm)</td><td>30 in (76 cm)</td></tr>
<tr><td>0.1</td><td>15 in (38 cm)</td><td>30 in (76 cm)</td></tr>
<tr><td>1</td><td>46 in (117 cm)</td><td>8 ft (2.4 m)</td></tr>
<tr><td>10</td><td>12 ft (3.7 m)</td><td>24 ft (7.3 m)</td></tr>
<tr><td>100</td><td>38 ft (11.7 m)</td><td>77 ft (23.4 m)</td></tr>
</table>
Note: Field strengths from transmitters, as determined by an electromagnetic site survey, should be less than the compliance level of 3 V/m.</td></tr>
</table>

If the MiniCAT™ is suspected of causing harmful interference to other surrounding equipment the customer or user is encouraged to try to correct the interference by one or more

of the following methods:

- Turn the MiniCAT™ off and on to verify that the interference is coming from the MiniCAT™.
- Move the other equipment farther away from the MiniCAT™.
- Connect the other equipment into an outlet on a circuit different from that to which the MiniCAT™ is connected.
- Contact Xoran Technologies customer support for additional assistance.

1.5 Cleaning and Service

Cleaning Schedule

It is recommended that the equipment be cleaned and disinfected in the following manner:

- Between Patients:
  - Clean patient head holder, head strap and chair with alcohol. **Do not spray.**
- Daily:
  - Clean dust from surfaces by wiping with a dry or slightly damp cloth.
- Monthly:
  - Check for defective X-ray indicator lights and sounds.
  - Gently vacuum dust from fans behind acquisition workstation and server (if applicable).
  - Open server front panel and gently vacuum out dust accumulation (if applicable).

Service and Maintenance

There are no user-serviceable parts on the MiniCAT™. It is recommended that the equipment be inspected and serviced annually. Inspection and service must be performed by Xoran Technologies, Inc. or other technician licensed and qualified to service this equipment.

Service/preventative maintenance for the first year of equipment operation is covered by Xoran Technologies under the equipment warranty. Ongoing service and preventative maintenance can be purchased under a service agreement with Xoran Technologies.

It is the responsibility of the user to ensure that the equipment is maintained in compliance with the manufacturer recommended maintenance schedule. The manufacturer and the

assembler/installer can not be held responsible for the failure of the owner/user to have the manufacturer's recommended maintenance performed.

1.6 Data Backup

Every effort has been made to ensure that patient data is stored safely on the MiniCAT™. However, it is recommended that periodic backup is performed to prevent data loss in the event of catastrophe or system failure. It is the user's responsibility to ensure adequate data backup is performed.

Call Xoran Customer Service for recommendations on how to perform data backup most effectively.

1.7 Regulatory Compliance

Regulatory Compliance Information (USA and Canada)

MiniCAT™ has been tested and/or evaluated against and found compliant with the following IEC standards/requirements:

- IEC 60601-1
- IEC 60601-2-32
- IEC 60601-2-44
- IEC 60601-1-1
- IEC 60601-1-2
- CAN / USA 60601-A1

Equipment Class

- Protection against electric shock: Class I
- Applied part has degree of protection against electric shock: Type B Applied Part

MiniCAT™ has been tested and/or evaluated against and found compliant with the following IEC standards/requirements:

- Class of equipment against ingress of liquids: Ordinary Equipment, IPX0
- Radiated emissions: Class B
- LED - Class 2 / IEC 60825-1

2.0 INTRODUCTION

2.1 Welcome

Predrag ("Pedja") Sukovic
President/CEO

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May 1, 2006

Dear Valued Xoran Customer,

Thank you for purchasing the MiniCAT™ scanner.

We designed the MiniCAT™ scanner and the User's Manual to be easy to use. This User's Manual gives you chronological, step-by-step instructions for operating the scanner. It also provides you with technical specifications for the MiniCAT™ scanner.

To ensure the safe and proper use of your new scanner, please make sure that you read and understand this User's Manual before operating the scanner and follow the User's Manual's operating and safety instructions when using the scanner. The instructions in this User's Manual are meant to supplement your Xoran on-site training, your radiation safety training as required by your State's Radiation Safety Regulations, and your own professional training and expertise.

Customer Service and Support is our #1 priority. We want to do everything we can to help you use your new MiniCAT™ scanner in a safe and efficient manner.

If you have any questions, please call us at: 800-70-XORAN (800-709-6726). Our Customer Service Engineers will be happy to help you.

Sincerely,

Predrag Sukovic

President/CEO

2.2 MiniCAT Overview

What is a MiniCAT™?

Xoran Technologies has created a revolutionary compact CT scanner for sinuses and ears that is specifically designed to be used by physicians at the patient's point of care. Unlike large full-body CT scanners, the MiniCAT™ allows patients to sit comfortably upright in an open, patient-friendly design. This is a significant feature, because many patients complain of feeling claustrophobic in traditional CAT scanners. Adult sinus and temporal bone scans are collected in a single 360° rotation around the head that takes only 40 seconds. Children's scans take 20 seconds, and the scanner has a significantly lower radiation dose than full-body scanners. Doctors get instant, high-quality images on a computer monitor allowing them to diagnose problems and begin treatment as quickly as possible.

2.3 Manual Updates

Online Manual

The most up-to-date version of this manual can always be viewed online: http://www.xorantech.com/Help/MiniCAT/HTML/index.html Navigate the online manual by clicking chapter headings in the table of contents (on the left).

Tip: From the MiniCAT™ software, press the F1/HELP key at any time to launch the online manual.

Hard Copy Manual

For a hardcopy, download the latest version in PDF format at the following link: http://www.xorantech.com/Help/MiniCAT/MiniCAT Users Manual.pdf. This manual is originally written in the English language.

2.4 Scanner Hardware

The following diagram shows the MiniCAT™ scanner hardware with the main components identified. These components will be referred to throughout this manual.

In addition to the scanner hardware shown in the above picture, MiniCAT™ also ships and is installed with an acquisition workstation and server (optional) which are shown in subsequent sections of this User's Manual.

2.5 Other Components

Following is a list of accessories that accompany the MiniCAT™. Call Xoran Customer Service for replacements as needed.

Part Number	Description
20007	Phantom Holder
20008	Seat Cushion
20009	MiniCAT™ User's Manual

Part Number	Description
20011	Workstation with Keyboard and Mouse
20012	Server
20013	Xoran Labeled CD Stack
20014	Foam Spacers - Calibration Phantom
29045	Operator Control Box
29080	Patient E-Stop
29081	Elevation Remote
30001	Accessory Bin
30004	Ethernet Cable
30005	DGL-4100 Broad Band Router
30006	Foot Stool
30007	HP96 Black Printer Ink
30008	HP97 Color Printer Ink
30009	HP 6540 Printer
30010	HP 6940 Printer
30011	HP Premium Plus Photo Paper
30012	Workstation Monitor
30014	USB 2.0 AB Printer Cable
30016	Tripp-lite UPS Battery Backup
30017	Operator's Desk
30018	Water Phantom
30019	Booster Seat
30020	Extension Strap for Booster Seat
30021	Chin Strap
30022	Forehead Strap - Adult

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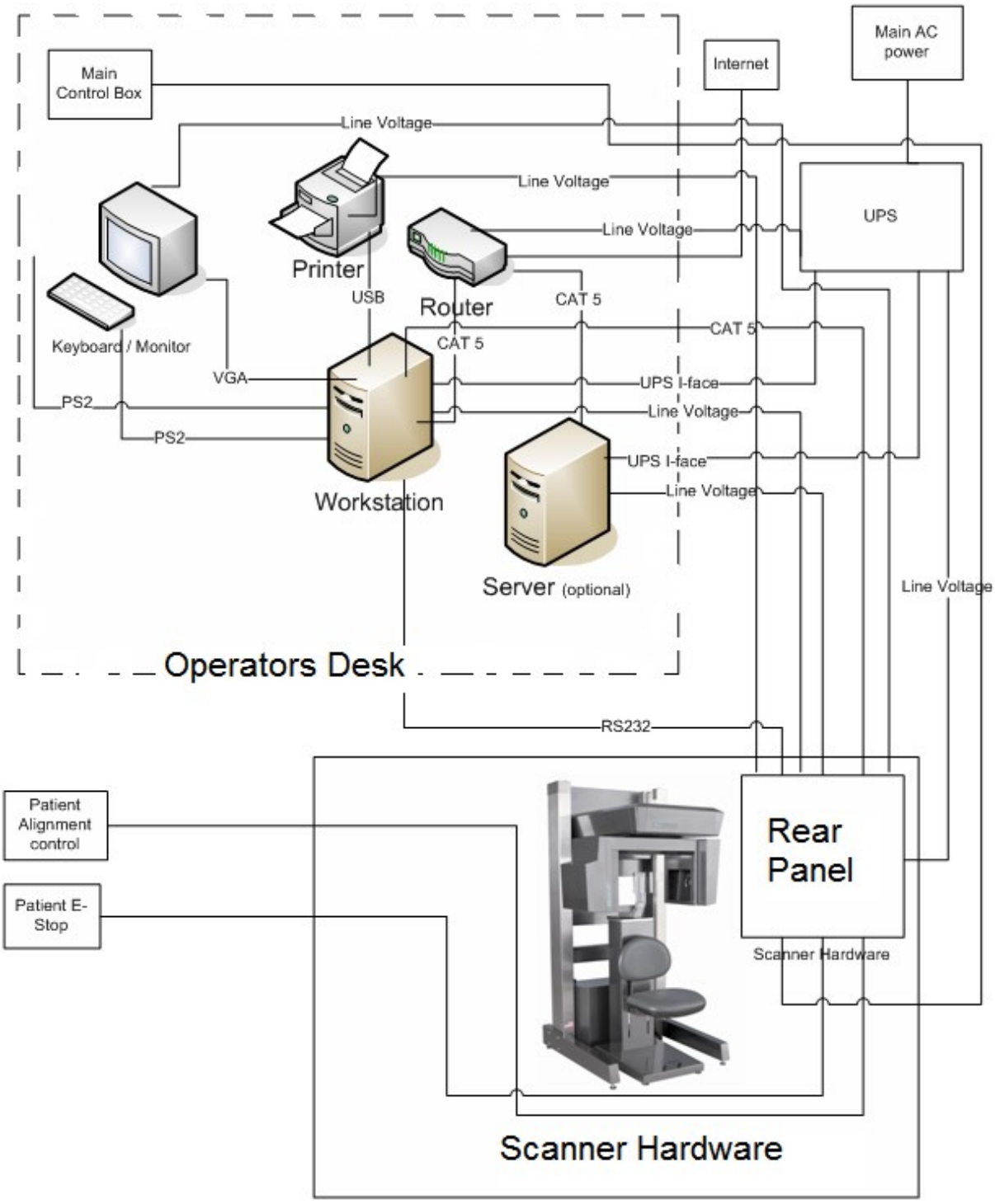
Part Number	Description
30023	Forehead Strap - Child
30024	Linksys 5-Port Network Switch

Warning: Only use original accessories provided during installation of the equipment. Do not use any other parts or accessories.

2.6 Connectivity Diagram

Power cables from the workstation (and server if applicable) are connected to the back of the MiniCAT™ scanner hardware. Do not alter this configuration.

All peripheral devices used with the MiniCAT™ should be certified to meet the requirements of standard IC60950-1, including modems and networking/ethernet cards and devices.


Main Control Box
Internet
Main AC power
Line Voltage
Line Voltage
Line Voltage
UPS
Printer
USB
Router
CAT 5
CAT 5
CAT 5
Keyboard / Monitor
VGA
UPS I-face
PS2
Line Voltage
PS2
UPS I-face
Line Voltage
Workstation
Server (optional)
Line Voltage
Operators Desk
RS232
Patient Alignment control
Patient E-Stop
Rear Panel
Scanner Hardware
Scanner Hardware

2.7 Operation Sequence

Overview of Steps for Performing a MiniCAT™ Scan

Note: This page is meant only as an overview or reminder. Please attend MiniCAT™ training with a qualified instructor and read the complete MiniCAT™ user's manual before operating the equipment.

1. System Startup. (Chapter 3)

→ Scanner should be warmed up for one hour before calibrating or scanning.

2. Perform a Daily Calibration. (Chapter 4)

→ Be sure to remove the head holder!

3. Enter Patient Information (Chapter 5)

4. Click [Acquire New] and Select Imaging Protocol (Chapter 6)

→ Scanner will initialize for scanning, may move and make a sound.

5. Seat and Position Patient (Chapter 6)

→ Have patient remove jewelry, glasses, hair accessories, etc.
→ Adjust height of patient chair until top of ear is properly aligned in head holder.
→ Use laser cross-hair to position patient based on imaging protocol:
- Sinus Scan: Laser on High Cheekbone
- Temporal Bone Scan: Laser on Tragus

6. Take a Scout View to Confirm Patient Position (Chapter 6)

→ Have patient relax, close eyes, remain still and avoid talking, chewing and swallowing.
→ Ask patient to remain seated until instructed to exit scanner.
→ Perform a Dry Run to familiarize patient with scanner movement.

7. Click [Start Acquire] to initiate scan (Chapter 6)

→ Scan will be performed, and overhead gantry will rewind.
→ When gantry stops moving, instruct patient to exit scanner.

8. View images (Chapters 7)

→ Use MPR view and other tools to scroll through scan volume.

9. Output images (Chapter 8)

→ Images can be sent to printer or other media.

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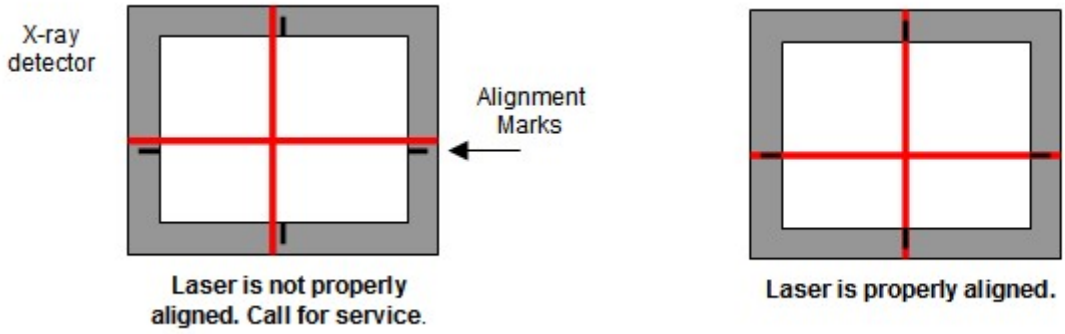
2.8 Laser Alignment

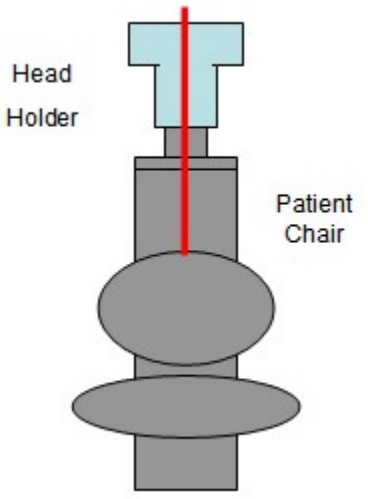
Warning: Class II laser light. Do not stare into the beam.

To confirm alignment light accuracy:

- Turn off lights.
- Press and hold **[Alignment Light]** button to turn on laser.
- Side lasers should align with the marks on perimeter of X-ray detector.



- Front laser should hit the center of the headrest.



Note: If lasers are not aligned properly, call Xoran Customer Service.

3.0 STARTUP AND SHUTDOWN

3.1 Emergency Shutdown

Emergency Shutdown

In the case of an emergency, the system rotation can be stopped and X-ray emission can be halted by pressing the **EMERGENCY STOP (E-Stop)** button. The operator E-Stop is located on the Main Control Box on the operator's desk. The Patient E-Stop is located on the Patient Control Box which can be held by the patient during the scan.

Patient E-Stop

Operator E-Stop

After pushing the E-Stop, the overhead gantry can be manually rotated if needed so that the patient can safely exit the scanner.

Warning: Turn E-Stop clockwise to reset. It is also recommended to restart MiniCAT™ software after resetting the E-Stop.

3.2 System Startup

Warning: It is recommend that the scanner remain on at all times. If the scanner has been shut down for any reason, please allow one hour for the scanner to warm up before scanning patients to ensure the best quality images.

Both the MiniCAT™ scanner hardware and the workstation must be turned on for the system to function properly.

Turn on the Workstation

The workstation computer controls the MiniCAT™ system hardware and software.

Press the power button to start the workstation.

Also, turn on peripheral devices such as the workstation monitor, printer and server (if applicable) at this time.

Turn on MiniCAT™ Hardware

To turn on the system, push the green **ON** button on the Main Control Box.

The Main Control Box should be located on the operator's desk. The lights on the Main Control Box represent the following:

POWER: The system is turned on.

READY: The system is ready to perform a scan.

X-RAY ON: The X-ray source is on (emitting radiation).

FAULT: When lit, this light indicates that the X-ray has timed out. Please contact Customer Service at 800-70-XORAN.

FAULT: (flashing) When rapidly flashing, this light indicates a hardware initialization problem. Please follow the system shutdown procedure, followed by the system startup procedure. If the problem persists, Please contact Xoran Customer Service for assistance.

Note: The same light configuration is on the front overhead cover of the machine (except the fault light).

Note: The Yellow **OFF** button on the Main Control Box can be used to turn off the MiniCAT™ scanner hardware. It is recommended that the system be left on at all times.

Launch MiniCAT™ Software

Tip: Make sure the workstation monitor is turned on!

1. Double click on the MiniCAT™ icon on the desktop.

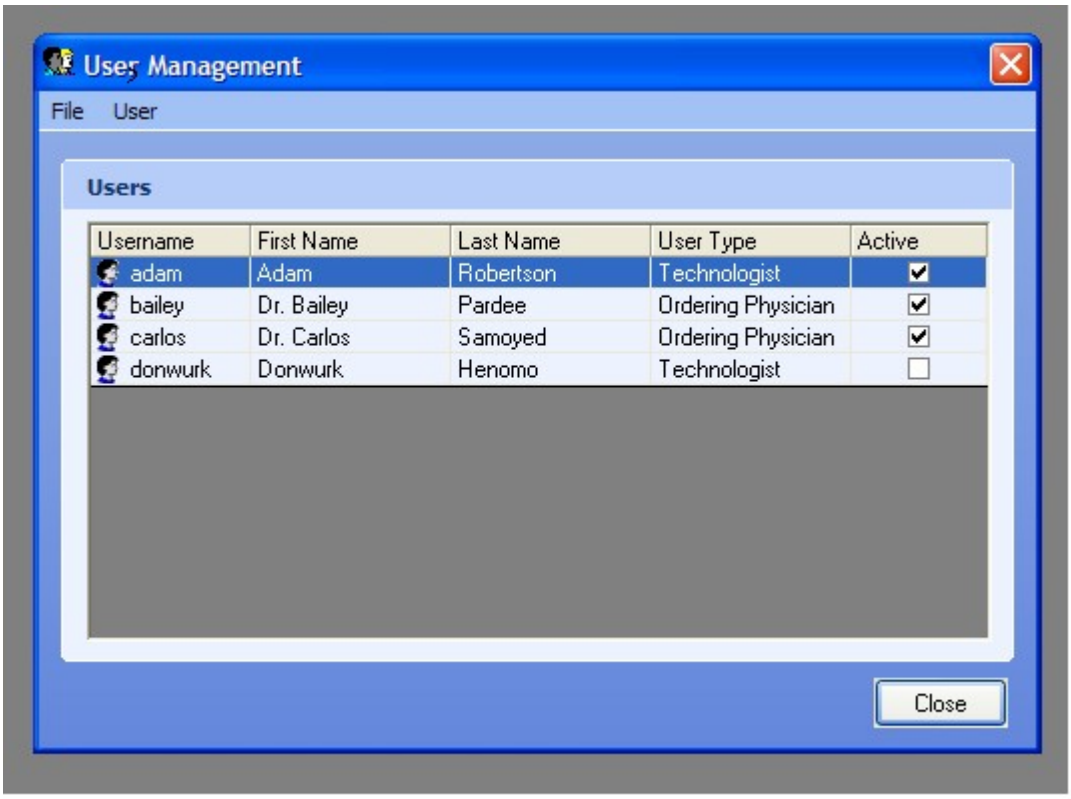
2. System users must log on to operate the system. Enter username and password.

3. *Patient Database* window will open.

3.3 User Management

User Management

Any person operating the MiniCAT™ system is called a user. User information can be managed in the *User Management* window. To launch, select the **User Management** option from the **View** menu in the application.



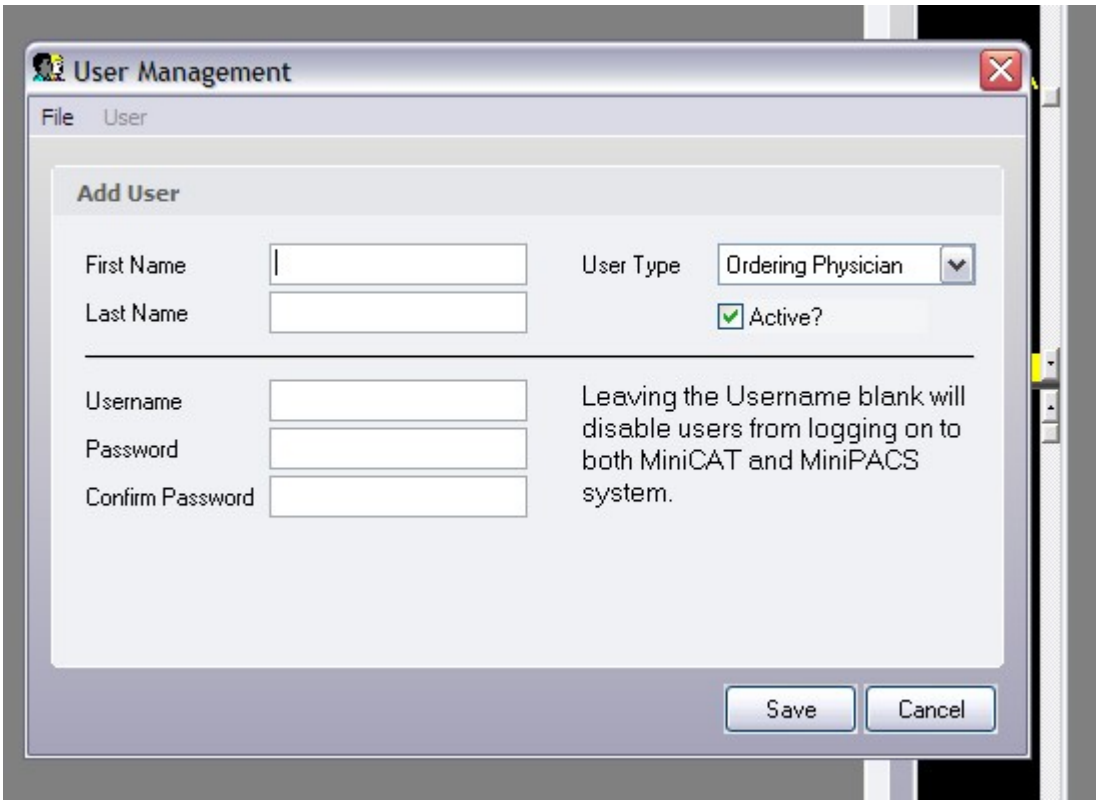
The most common User Management action are listed below:

- **New User**: From the **User** menu select **New User**. Fill in the user information into the fields.

- **User Type**: Users of the MiniCAT™ system are classified as either an "Ordering Physician" or "Technologist". Each patient study should be assigned to an ordering physician.
  Note: When using MiniPACS™ online service to view patient studies over the internet, the ordering physician must be logged on to view studies assigned to him or her.

- **Active**: Active users have the ability to log onto the system and use the MiniCAT™ software. Clearing the **Active** check box "deactivates" the user. This prevents this user from using the scanner but preserves the user data for record-keeping and/or future reactivation purposes.

- **Delete User**: A user account can be deleted from the system by right-clicking a user's name and clicking **Delete**. All information about that user is removed from the system.

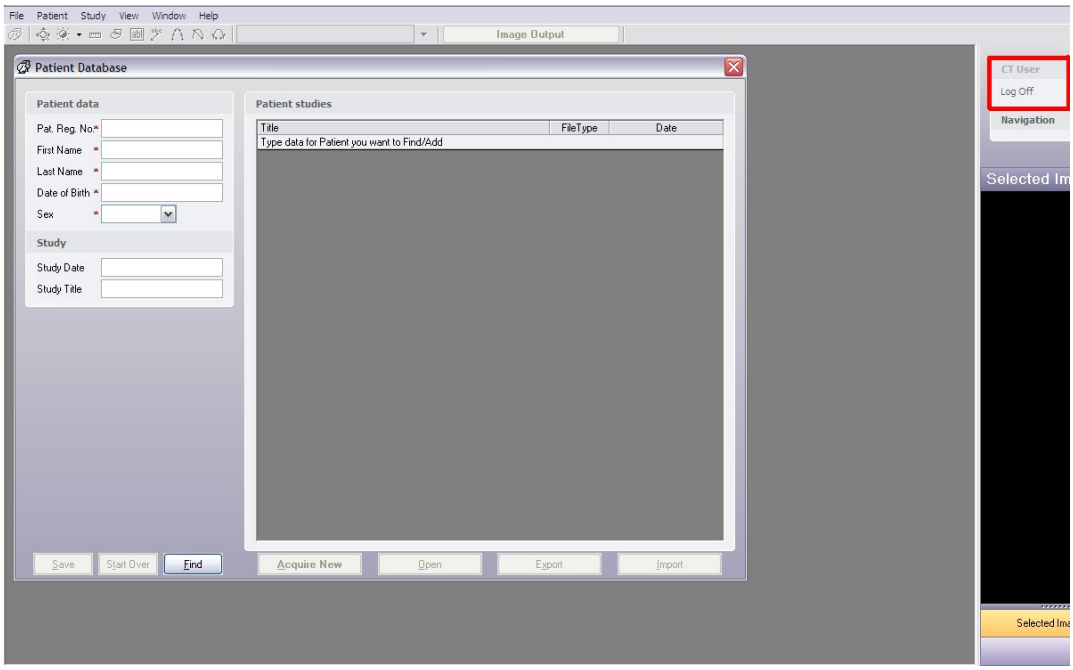


3.4 System Shutdown

Warning: It is recommend that the scanner remain on at all times. If the scanner has been shut down for any reason, please allow one hour for the scanner to warm up before scanning patients to ensure the best quality images.

User Logoff

The current user is shown in the upper right corner of the MiniCAT™ software. To log out, click on the words **Log Off**.



Exit Software

To close MiniCAT™ software, select the **Exit** option from the **File** menu.

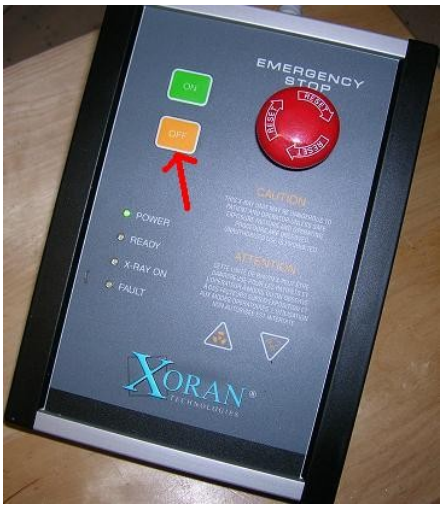
Turn Off Workstation

Note: Most MiniCAT™ users keep the workstation powered on at all times. However, if the installation site is subject to frequent power surges, we recommend that the computer be turned off at night to protect the system and prevent data loss.

1. Click the **Start** icon on the bottom left of the main computer screen.
2. Click **Turn off Computer**.

Turn Off Scanner

To turn off the scanner, push the yellow **OFF** button on the Main Control Box



3.5 UPS

Uninterruptible Power Supply

The MiniCAT™ system is installed with a UPS (Uninterruptible Power Supply) which contains a backup battery with enough capacity to complete one scan. If the facility power goes out while a scan is in progress:

- The system will continue to be powered by the UPS battery.
- The scan in progress will complete as usual.
- No information will be lost.
- The UPS will beep indicating that battery is being consumed.

Note: When the scan is complete, it is recommended that the system be shut down until continuous power is restored.

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4.0 DAILY CALIBRATION

For best image quality, the MiniCAT™ system should be calibrated daily. Calibration should only be performed after the system has been powered on for at least one hour. We recommend leaving the MiniCAT™ system on overnight and calibrating first thing each morning.

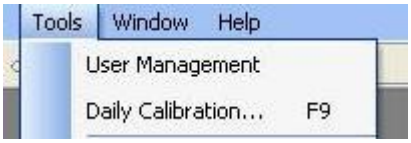
Warning: X-rays will be emitted during daily calibration

Daily Calibration Procedure

1. The imaging area between the X-ray source and X-ray detector must be free of all objects. Remove the head-holder, phantom holder and any phantom that might be present before continuing.

   Caution: The patient must not be in the scanner.

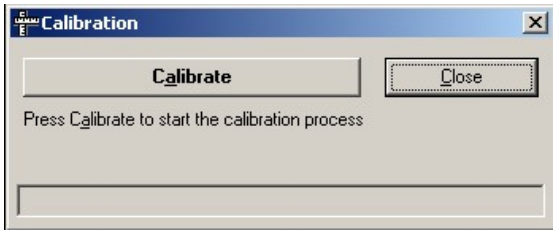
2a. Select the **Daily Calibration** option from the **Tools** menu.



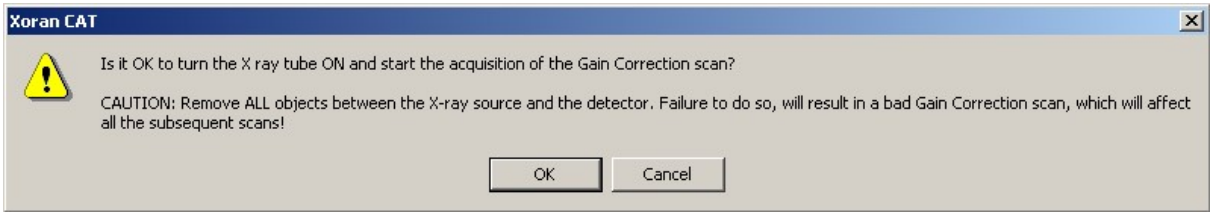
NOTE: To calibrate with prior versions of MiniCAT™ software, select the **Calibration** option from the **View** menu.

2b. Alternatively, you can push the F9/CAL key.

3. A message will appear, prompting to start the calibration process. Click **Calibrate** to begin.

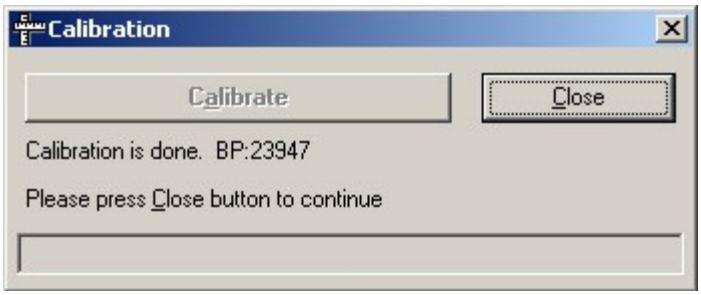


4. A message will appear, asking you if it is **OK** to turn on the X-ray source. Ensure that you are behind the radiation barrier and click **OK**.


Xoran CAT
Is it OK to turn the X ray tube ON and start the acquisition of the Gain Correction scan?
CAUTION: Remove ALL objects between the X-ray source and the detector. Failure to do so, will result in a bad Gain Correction scan, which will affect all the subsequent scans!
OK
Cancel

Warning: It is the user's responsibility to ensure that proper radiation safety procedures are in place before firing the X-ray source.

5. Remain behind the radiation barrier until a message appears, indicating the calibration is complete. Click **Close** to finish the process.



5.0 PATIENT DATABASE

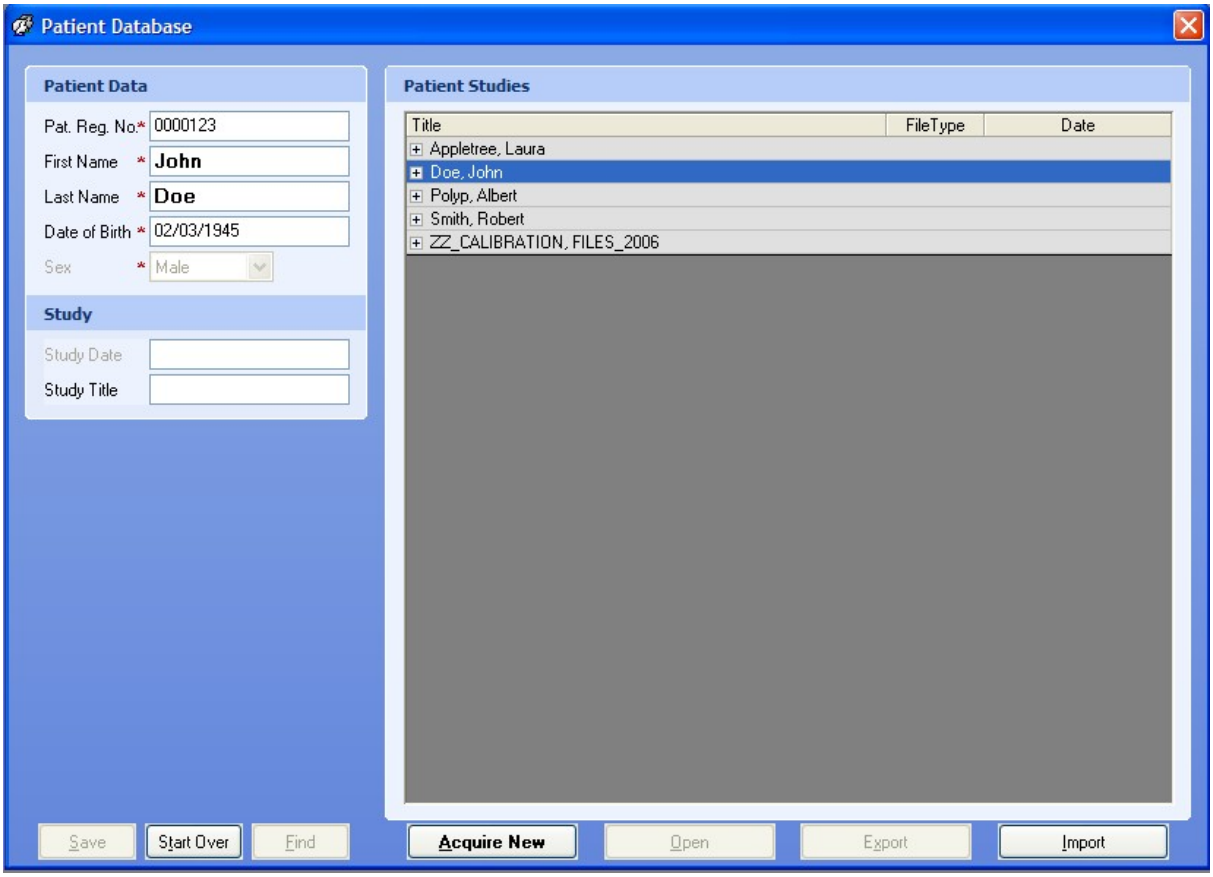
The Patient Database is the user interface to patient records and studies.

5.1 Patient Database

Launch Patient Database

The *Patient Database* window is automatically opened when the MiniCAT™ software application is launched.

Tip: The Patient Database can also be accessed at any time by pressing the **F8** key or the icon in the toolbar.



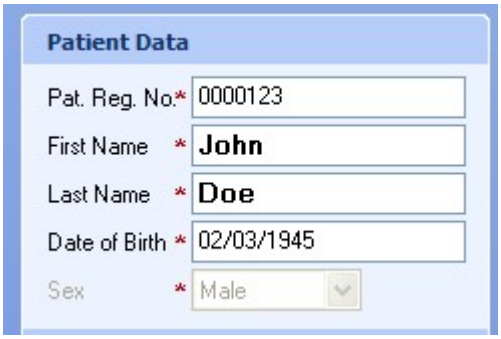
5.2 Enter New Patient

Enter New Patient

1. To enter a new patient, click the **Start Over** button in the lower-left portion of the *Patient*

Database window.

2. Enter patient data in the fields. Required information is marked with an asterisk. Enter the patient's date of birth in mm-dd-yy or mm/dd/yy format.



Note: Do not enter anything in the **Study Date** and **Study Title** fields. This information will be filled out automatically when the scan is performed.

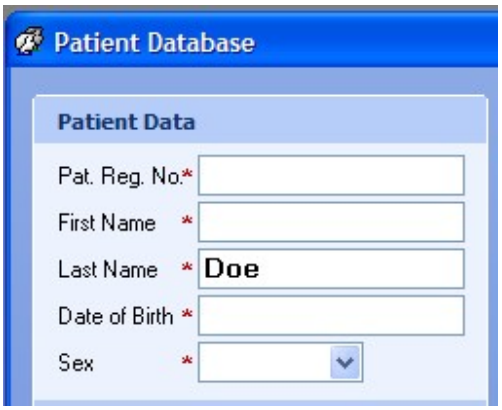
3. After entering the information in the Patient Data box, save it by clicking **Save** on the bottom left of the screen.

5.3 Find Existing Patient

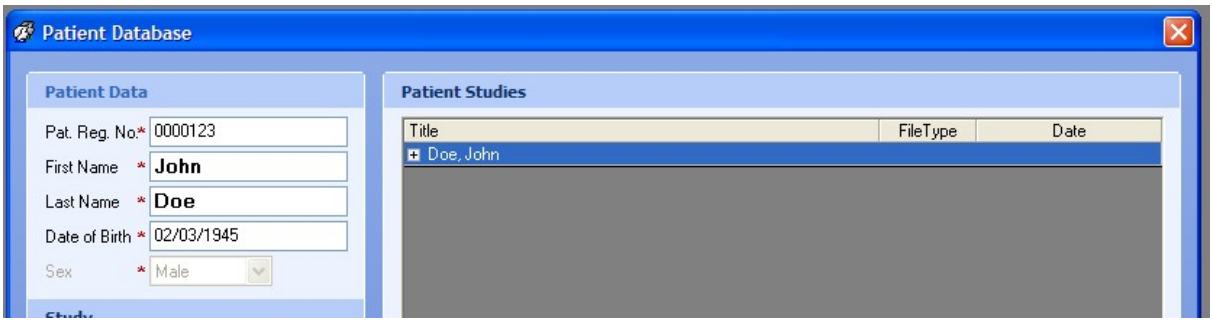
Find Existing Patient

1. Click **Start Over**. The **Find** button will be enabled and the Patient Data fields will become blank.

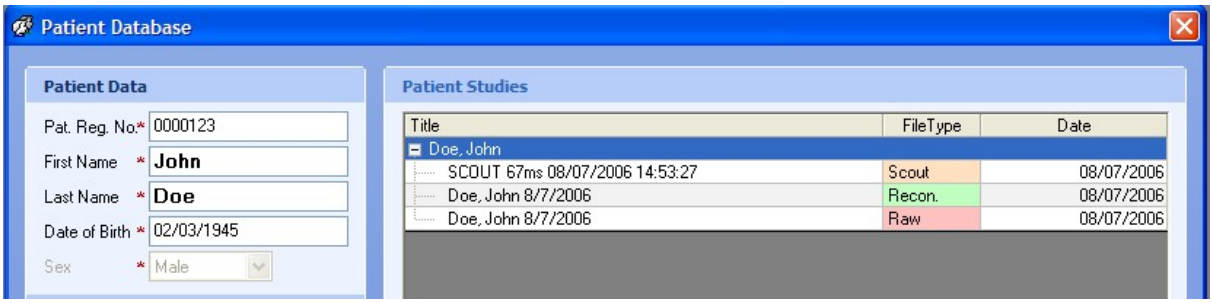
2. Patient records can be searched by name, number, birthdate or study date. Enter any known information in the Patient Data fields. For example, type the first few letters of the patient's last name.



3. After you enter your search criteria, click **Find**. A list of matching patients will be displayed.



4. Click on the **[+]** to view studies listed under this patient's name.



There are three types of study files. They are described below.

Study File Type	Description
Scout	A Scout is a single X-ray image that is used to ensure that the patient is positioned properly for the scan.
Raw	Raw data is a sequence of images collected by the MiniCAT™ system

Study File Type	Description
	during an acquisition. This raw data is "reconstructed" using a tomographic algorithm to create 3-D imagery.
Recon	The final result is known as the Reconstruction. This 3-D volume imagery can be viewed as a series of coronal, sagittal or axial slices, as well as in many other ways.

5. To open a study for viewing, double-click on its title.

Note: Refer to Chapter 7 for more information on viewing patient studies.

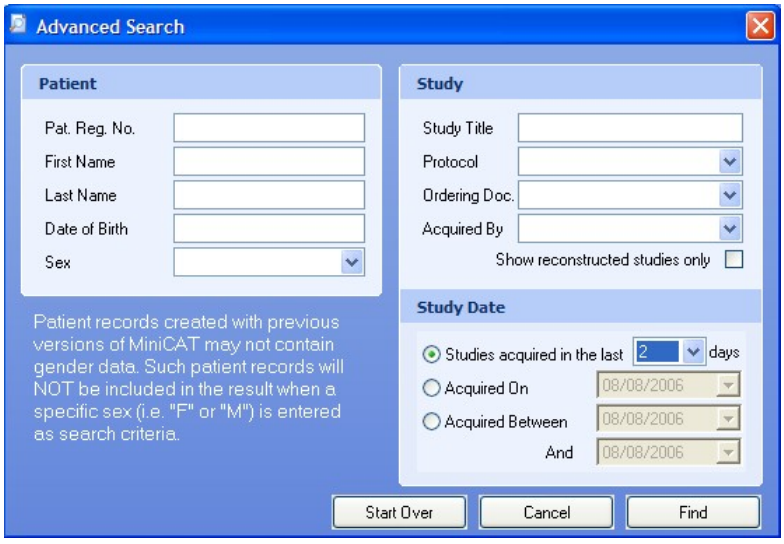
5.4 Advanced Search

Advanced Search

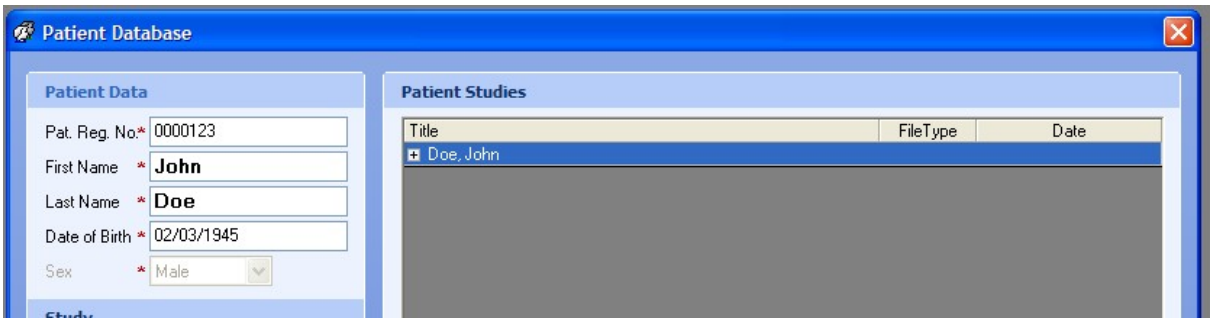
Patient studies may also be searched by ordering physician, imaging protocol, or a range of dates when the studies were acquired.

1. Click **Start Over** in the *Patient Database* window.

2. Select the **Advanced Search** option from the **Patient** menu.



3. Enter search criteria into the *Advanced Search* window and click **Find**. A list of matching patients will be displayed.



3. Click on the **[+]** to view studies listed under this patient's name.

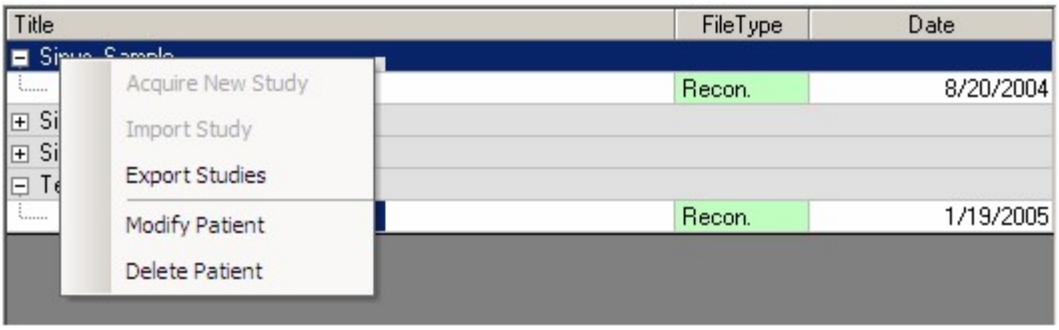
4. To open a study for viewing, double-click on its title.

Note: Refer to Chapter 7 for more information on viewing patient studies.

5.5 Delete Patient

Delete Patient

You can delete a patient by right-clicking on the patient's name and choosing **Delete Patient** from the drop-down menu.



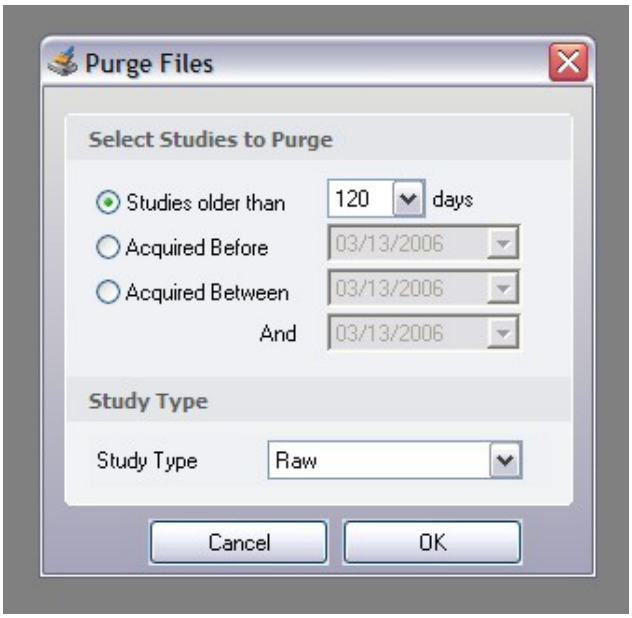
Warning: This action permanently deletes files from your system. Be sure to follow any required procedures for record retention and data backup before deleting patients.

5.6 Purge Files

Purge Files

To purge unneeded patients and studies in your system, follow these steps:

1. Select the **Purge files** option from the **File** menu.
2. Specify date interval to purge.
3. Select study type(s) to purge.
4. Press **OK** to remove the files permanently from your system.



Warning: This action permanently deletes files from your system. Be sure to follow any required procedures for record retention and data backup before purging files.

6.0 ACQUIRING IMAGES

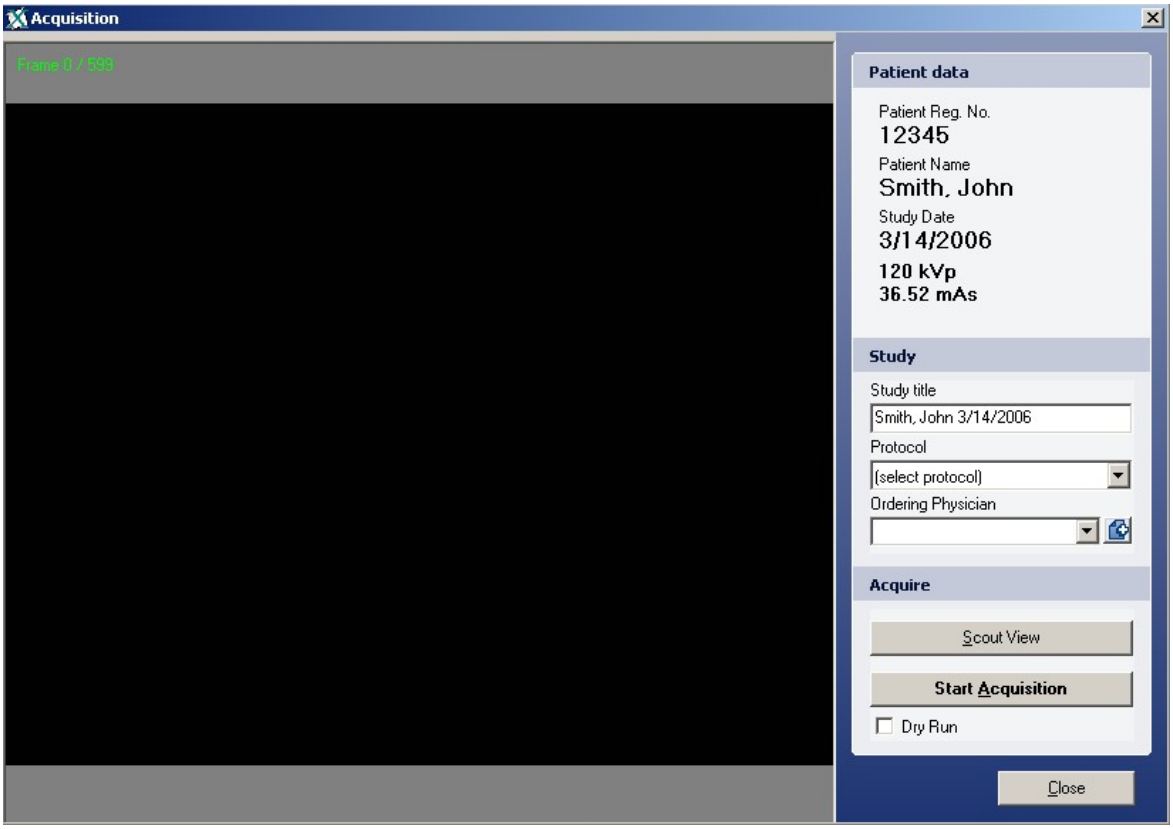
6.1 Select Imaging Protocol

Select Imaging Protocol

Important: Select protocol BEFORE seating the patient in the scanner

1. After entering new patient information or selecting an existing patient, click **Acquire New** .

2. The *Acquisition* window will appear.



3. Select the appropriate protocol from the **Protocol** menu. The standard protocol options are as follows:

Protocol	Description
Sinus 40s (Adult)	40-second imaging protocol, used for most adult sinus scans.
Sinus 20s (Pediatric)	20-second imaging protocol can be used for pediatric sinus scans or for adults where patient motion is an issue. Scan is faster and lower dose, but image quality will be somewhat reduced.
Sinus 10s (Follow-up)	10-second imaging protocol is a very low-dose scan which can used for follow-up, if desired.
Temporal Bone	Temporal bone imaging protocol provides higher spatial resolution than the Sinus 40s protocol, but field of view is somewhat smaller.
Xoran Factory Test	Used by Xoran engineer to perform factory setup/testing.
Resolution Test	Used by Xoran engineer to perform quality assurance.

Note for IGS Users: Additional protocols are available for creating images compatible with various image-guided surgery systems. If you have need for a protocol compatible with a specific IGS system, please call 800-70-XORAN (800-709-6726). A Xoran Customer Service representative will be happy to assist you.

4. Select the ordering physician.

   - To add a new ordering physician, click the **Add Physician** icon to the right of the Ordering Physician.
   - To change the ordering physician on a study, right-click a patient's name in the Patient Database and select **Ordering Physician**.

5. Position the patient (See section 6.3).

6.2 Educate Patient

For patient safety and to maximize the image quality of the CT scan, Xoran recommends the following information be provided to the patient, in addition to any state regulation requirements.

Prior to the scan:

- Remove jewelry, hair accessories and glasses.
- Sit upright, relax and face straight ahead.
- Hold the Patient E-Stop control in lap or hands (see below).
- Small lasers will be used for positioning (close eyes).
- A **Scout View** X-ray image will be taken to verify position.
- A **Dry Run** can demonstrate scanner movement without emitting X-rays.

During the scan:

- Sit as still as possible for best image quality.
- Avoid talking, chewing, yawning, swallowing, coughing or slouching.
- Breathe naturally moving head as little as possible.
- The scan takes 40 seconds for adults, 20 seconds for children.
- The overhead gantry will rotate. Close eyes to avoid following this motion with the head or eyes.
- The scanner makes a chirping sound as it performs the scan.
- In case of any problem, patient can stop the scan by pressing the **PATIENT EMERGENCY STOP (E-Stop)** button on the Patient Control Box.

After the scan:

- The overhead gantry will rewind when the scan is complete.
- Please remain seated until the operator instructs you to exit the scanner.

Patient E-Stop Control:

- Below is a picture of the Patient Control Box which includes the **PATIENT EMERGENCY STOP (E-Stop)** button.
- This can hang within easy reach of the patient or can be held in the patient's hand during the scan.
- Hit the big red button on the e-stop to stop the scanner if anything goes wrong.
- The gantry will stop moving and the X-rays will cease.

6.3 Seat and Position Patient

Seat and Position Patient

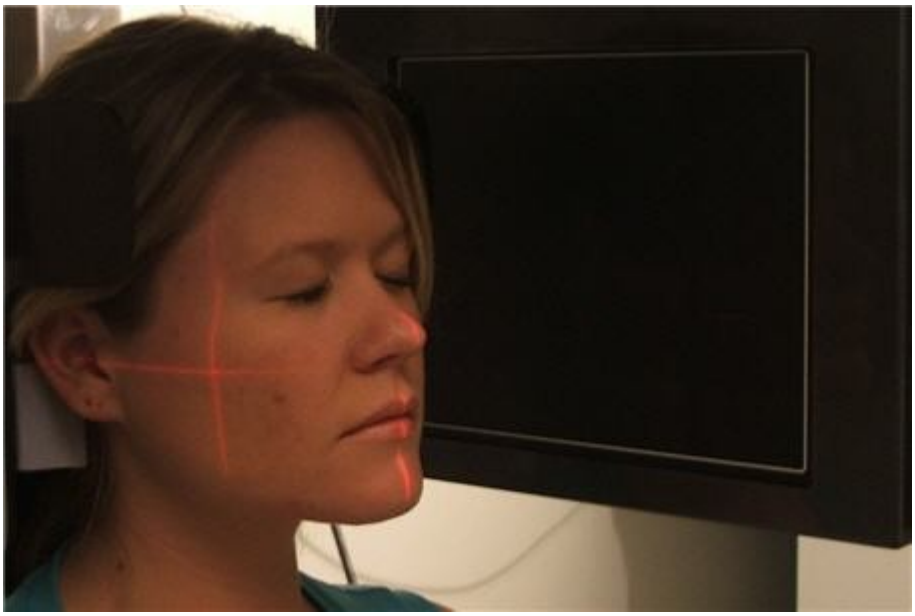
Important: Select protocol BEFORE seating the patient in the scanner.

1. After selecting protocol and educating the patient, seat the patient in the scanner. Adjust the chair so that the patient's head is positioned in the scanner as shown below.
   Note: Xoran can provide you with a booster seat for pediatric patients upon request.

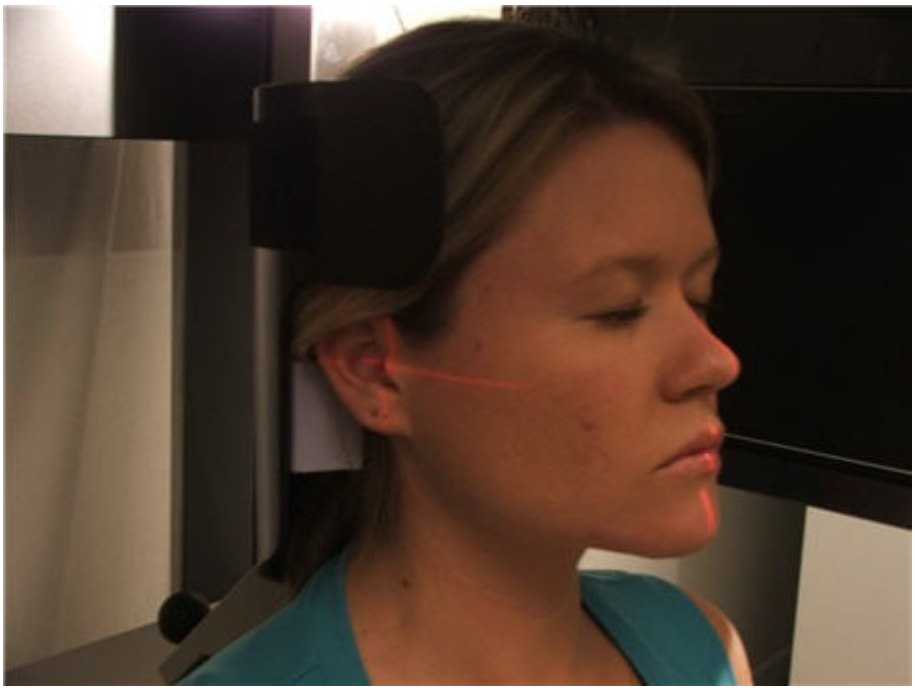
- Use the **Patient Align** arrows on the controller to move the chair up and down.

2. Make sure that patient's ear is aligned as shown below.

3. Instruct patient to close his or her eyes.
4. Press the **Alignment Light** button to turn on the alignment lasers.
    - Press button once to turn on the laser for a few seconds.
    - Press and hold for 3 seconds to turn on the laser for 5 minutes.
    - For a Sinus scan, the laser should project the crosshairs on the patient's high cheekbone as shown below.



- For a Temporal Bone scan, the laser should project the crosshairs on the patient's tragus as shown below.

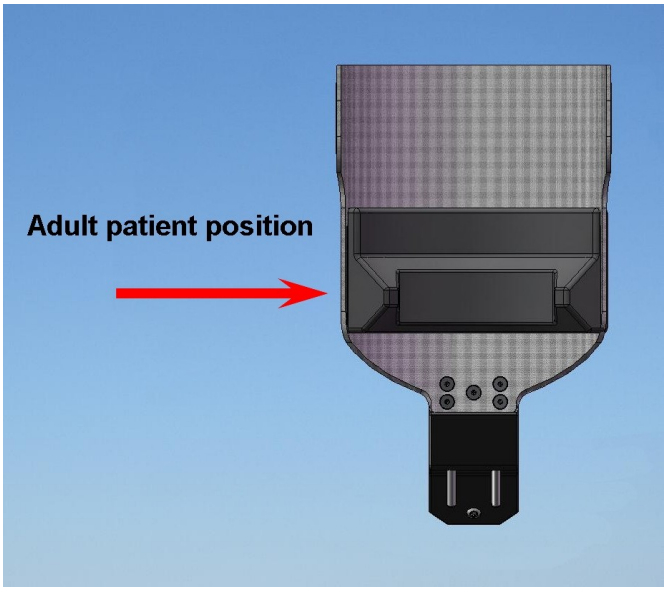


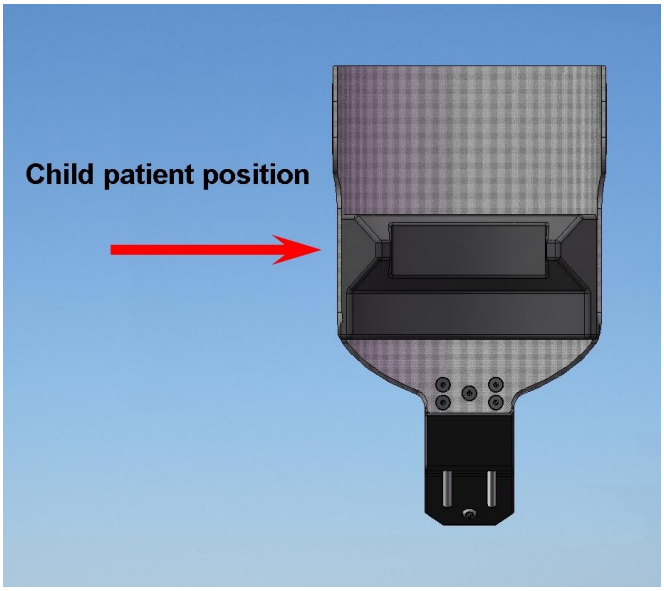
4. After the patient is properly positioned, secure forehead strap.

The new MK1 Carbon Fiber Head Holder ("MK1") was designed to control patient movement to optimize spatial resolution and image quality. Follow the directions below if your scanner

is equipped with the new MK1.

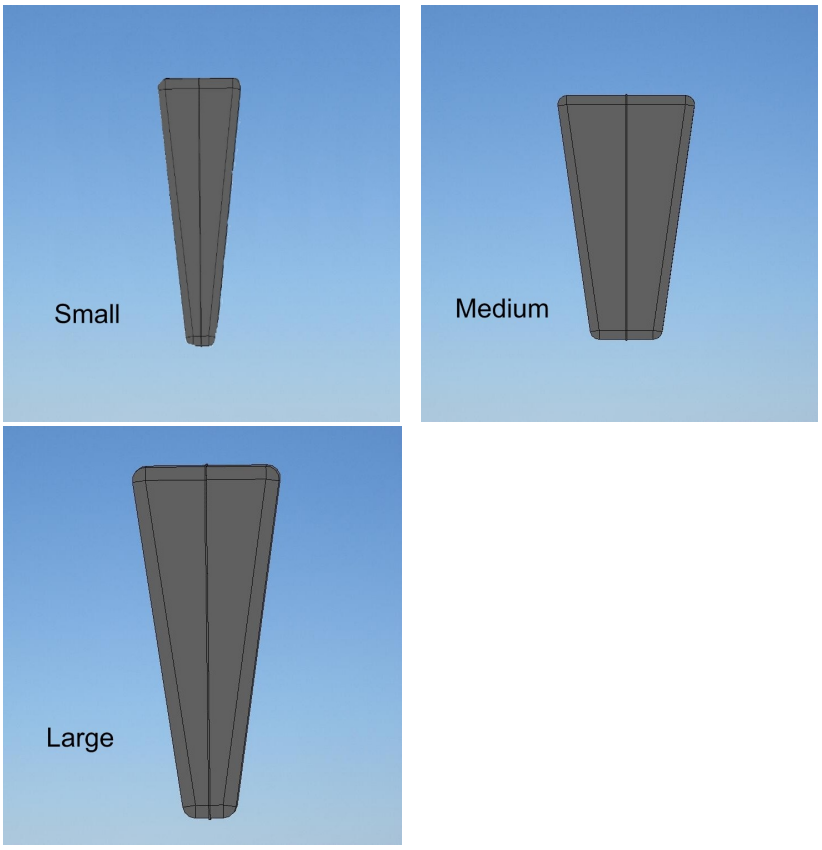
1. The neck pad in positioned in the bottom bracket for adults and the top bracket for pediatric patients. See example below.





2. Seat the patient so the neck pad sits comfortably at the curve of their neck. The patient's ears should be approximately .5 inches (1 cm) below the sides of the MK1.

3. Insert temple wedges squarely and securely on sides of head. Included with each MK1 are three pairs of different-sized temple wedges to fit patients of varying head sizes.



4. Secure forehead strap as shown below.

5. Remind the patient to remain still and relax while positioned in the scanner.

6.4 Dry Run and Scout View

Perform Dry Run

The **Dry Run** function rotates the overhead gantry without activating the X-ray source. This optional function allows the patient to become more familiar and comfortable with the system. This can help to reduce patient motion during the actual CT scan.

Important: Select protocol BEFORE seating the patient in the scanner.

1. Check the **Dry Run** box, and the **Acquisition** button will change to **Dummy Acquisition**.

2. Make sure that nothing, including any part of the patient, is in the path of the rotating overhead gantry.
3. Click **Dummy Acquisition**, and the gantry will rotate and rewind without firing the X-ray source.

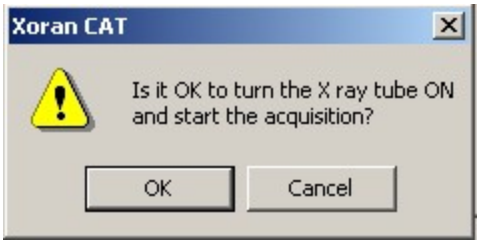
Acquire Scout View

A **Scout View** is a single lateral X-ray taken to verify that the patient is positioned properly.

Caution: Distances in Scout View image are not to scale. Scout View should not be used for any purpose other than positioning patient.

1. In the *Acquisition* window, click **Scout View**.

2. The following dialogue box will appear:



Important: Make sure that all required radiation safety procedures are complied with before proceeding.

3. Stand behind the barrier and click **OK**. The Scout View image will be acquired.

4. Check the Scout View to make sure that the following criteria are met. If the Scout View does not meet these criteria, the patient should be re-positioned.

   - For Sinus Scans:

     ➢ The sinuses are within the window.

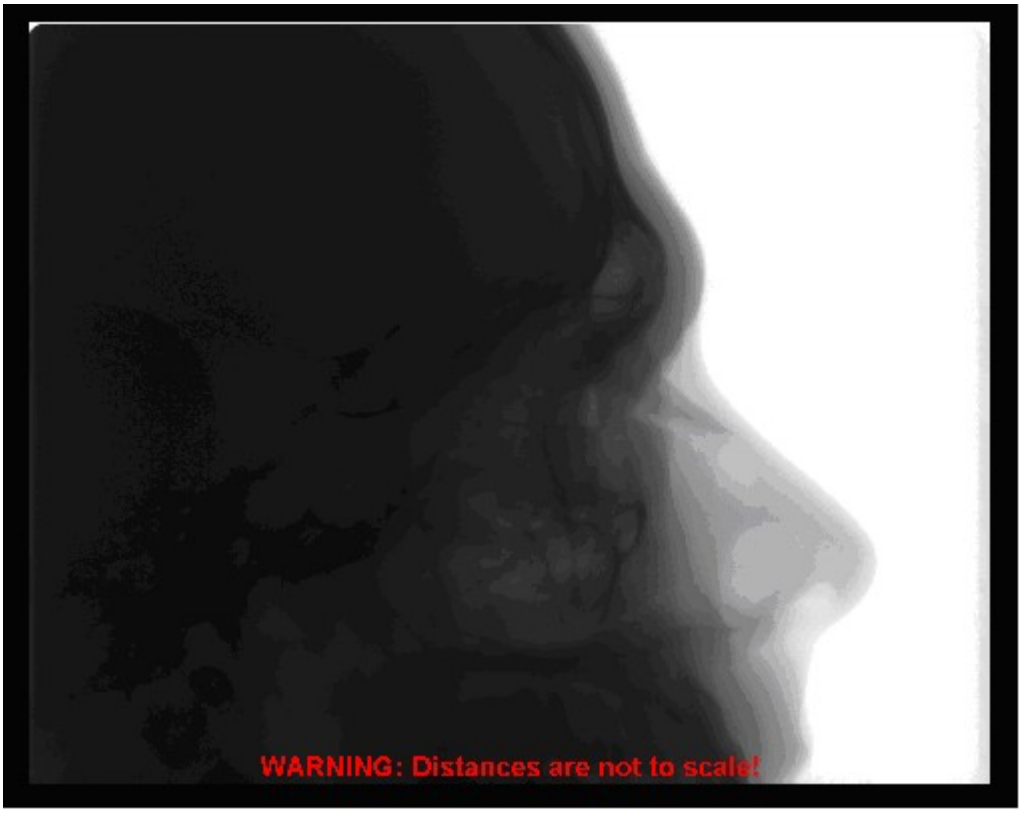
     ➢ Patient head appears facing sideways.

     ➢ Head is upright -- not tilting forward or back.

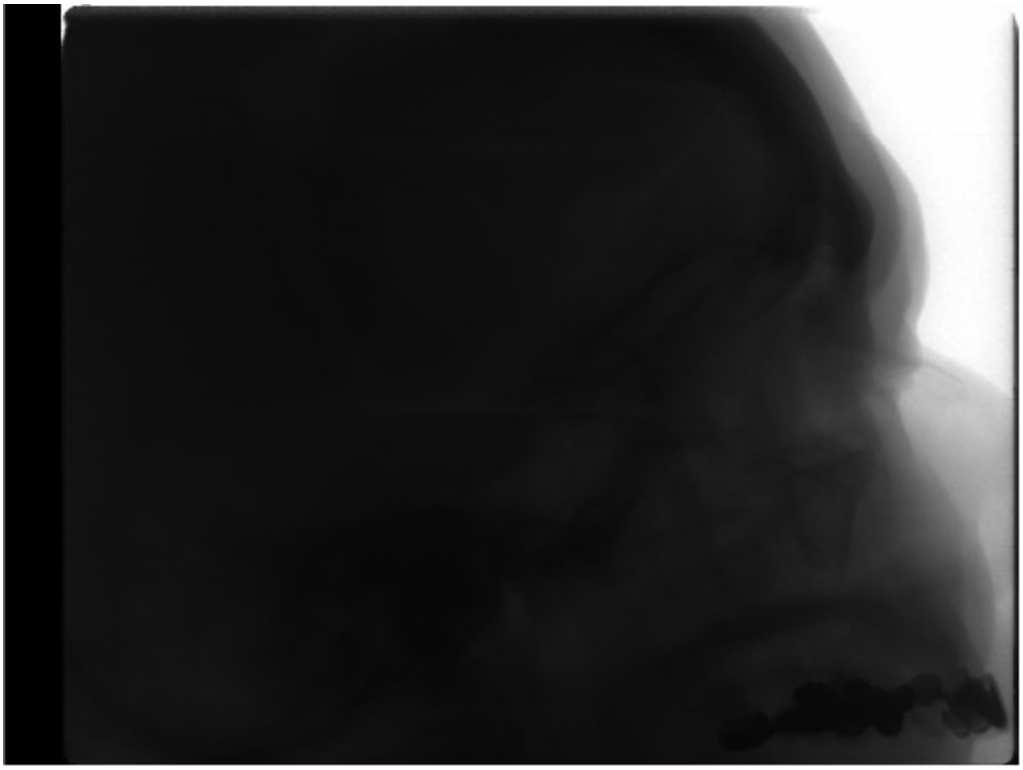
     ➢ There is space between the tip of nose and edge of the scout image.

- The top part of the upper lip is included.

An example of a good sinus Scout View is shown below:



An example of a poor sinus Scout View is shown below. Improper patient positioning is indicated by the visibility of the maxilla and upper teeth, and no space in front of the nose.



- For temporal bone scans:

  ➢The temporal bone area is centered in the scout view image.

  Note: For temporal bone imaging, a Scout View may not be the best method to assess a patient's positioning. Xoran recommends using the alignment laser lights.

6.5 Start Acquisition

Start Acquisition

1. After confirming that your patient is properly positioned, you are ready to acquire the CT scan.
2. Stand behind the operators barrier.
3. Click **Start Acquisition**.

The following message will appear:

Important: Make sure that all required radiation safety procedures are complied with before proceeding.

4. Remind the patient not to move.
5. Stand behind the barrier and click **OK**. Scan acquisition will begin.
   - The scan will take less than 1 minute.
   - The overhead gantry will rotate around the patient and a series of X-ray images will be acquired.
   - While the X-ray source is turned on, the system will make a chirping sound.
   - When the scan is completed, the overhead gantry will rewind to its original position.

Important: To stop the scanner in case of any emergency, press the **EMERGENCY STOP (E-Stop)** button.

6. Reconstruction will begin automatically. This takes approximately two minutes.

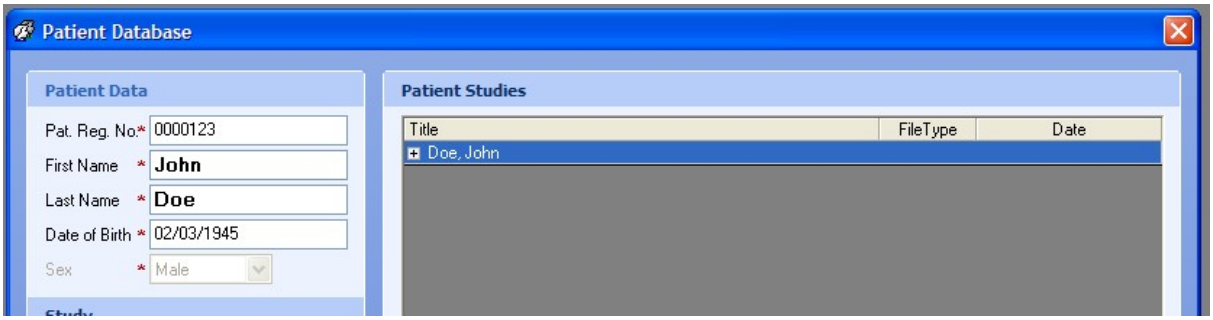
7.0 VIEW IMAGES

This chapter explains how to open a study, view images using various viewing options and tools, make annotations and select images for output.

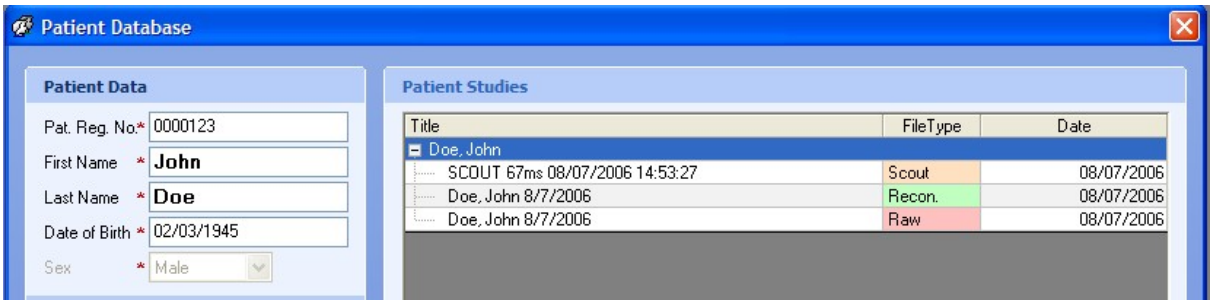
7.1 Open Study

Open Study

1. In the Patient Database, click the **[+]** next to the patient's name to view studies listed under that patient.

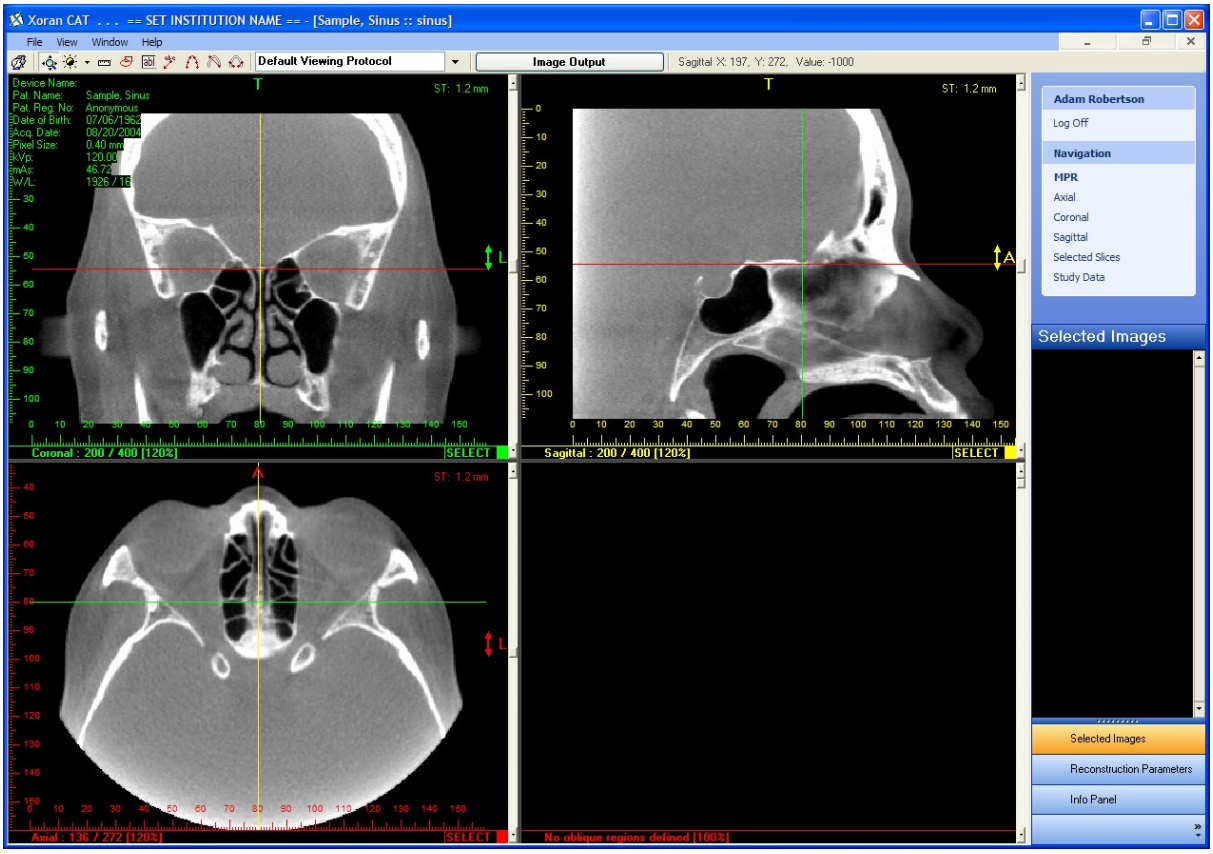


2. Double click on the **Recon** study you wish to view.



3. The study will open in the *Multi-planar Reconstruction (MPR)* window. This is the default setting for viewing and manipulating reconstructed images. Axial, coronal and sagittal planes are all visible at once.

   Tip: An overlay containing patient's name and other information appears in the upper left corner. Press <Ctrl-O> to toggle this text on and off.



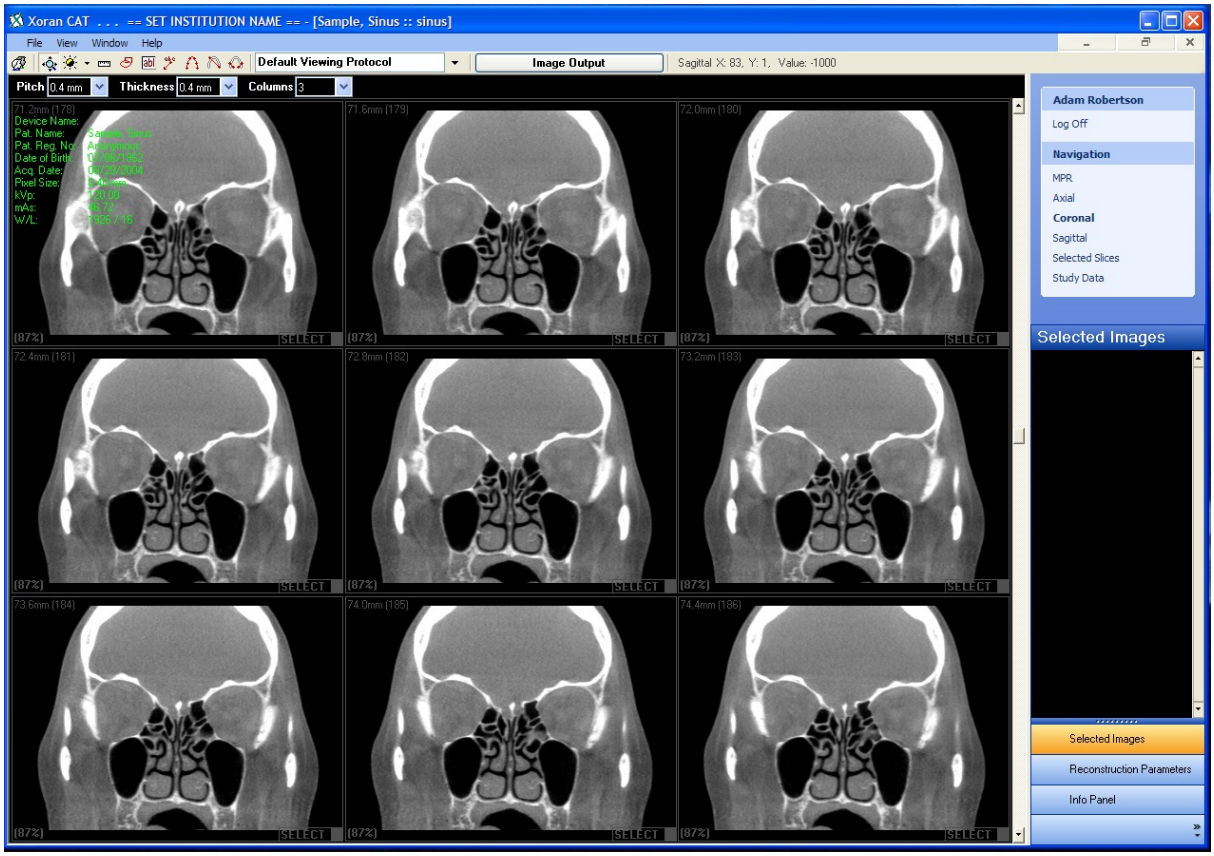
7.2 Viewing Options

The Navigation menu is located in the upper right corner. This menu contains several image viewing options. They are described below.

Image Viewing Option	Description
MPR	Three views are displayed at once. This is a powerful way to navigate the 3D scan volume.

Image Viewing Option	Description
Axial	A series of axial slices are displayed.
Coronal	A series of coronal slices are displayed.
Sagittal	A series of sagittal slices are displayed.
Selected Slices	User-selected slices are displayed (see next section on how to select slices).
Study Data	Auxiliary technical information is displayed here.

To change the view, click on the desired view option in the Navigation menu. For example, clicking **Coronal** will present the coronal series of slices as shown below.



7.3 Select Slices

Select Slices

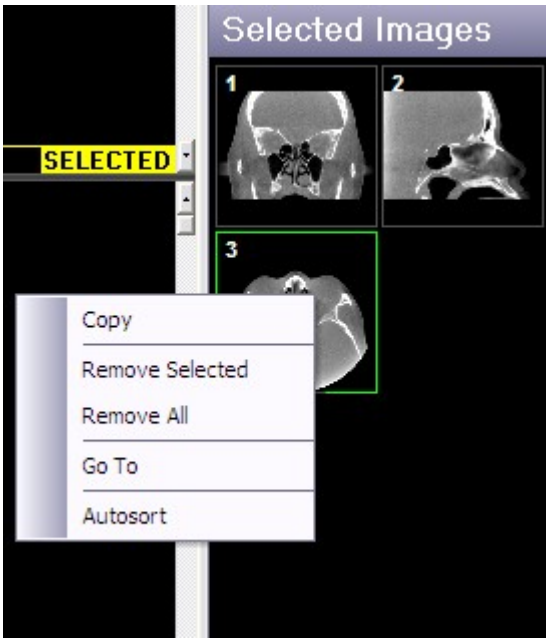
The **Selected Slices** view option allows you to view slices which have been selected by the user.

Note: Slices must be selected in order to be printed or exported.

1. Select a view option in the Navigation menu (Axial, Coronal, Sagittal, or MPR).
2. Click on the word SELECT in the lower-right corner of any image to select the image.

3. When an image is selected, the label will change to the word SELECTED.
4. Thumbnail views of Selected Images will appear in the *Selected Images* window.

5. Right-clicking on the **Selected Image** thumbnail will provide a menu of the following options:

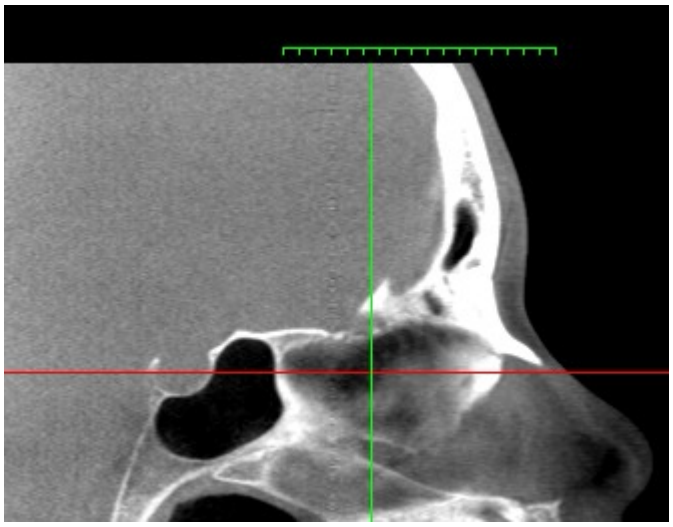


Slice Option	Description
Remove Selected	Removes a single image from the Selected Images series.
Remove All	Removes all images in the *Selected Images* window.
Go To	Displays the selected slice in MPR view.
Autosort	Orders your selected slices from anterior to posterior.

Tip: Hold down the SHIFT key to operate on multiple selected images at once.

Range Indicator

The Range Indicator is a convenient way to select a series of slices. It appears as a green bar with tick marks representing the locations of selected slices. The spacing between tick marks represents the pitch.



Click on the Range Indicator and drag it side to side to move the entire selected series all at once.

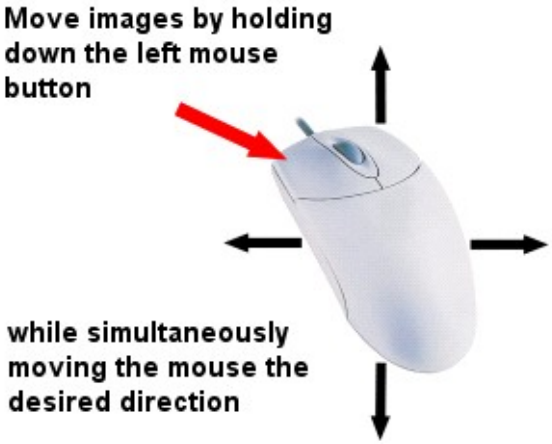
7.4 Viewing Tools

Zoom

- Select the Pan/Zoom tool from the toolbar.
- Place the cursor anywhere in the image (except over the colored lines).
- Left-click to zoom in.
- Right-click to zoom out.

Pan

- Select the Pan/Zoom tool from the toolbar.
- Place the cursor anywhere in the image (except over the colored lines).
- Click and hold down the left mouse button.
- Move the mouse to pan the image until desired position is achieved.

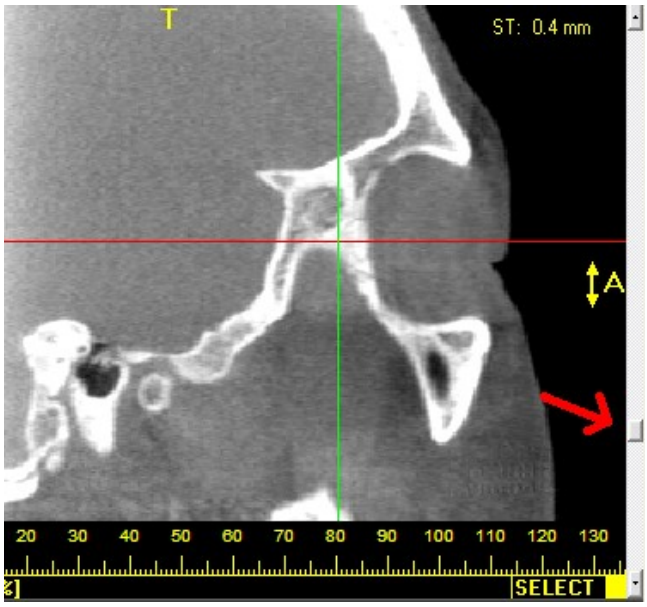


Scroll

There are 3 ways to scroll through the axial, coronal and sagittal slices:

- Using the mouse wheel.

- Using the slider.

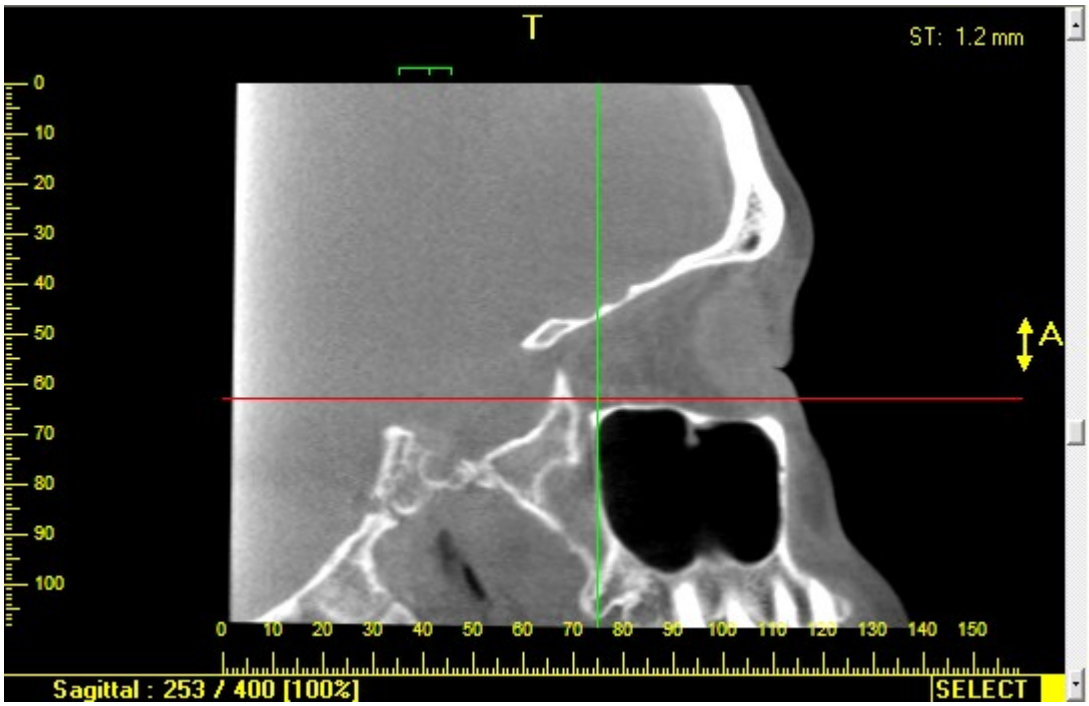


- Using cut-plane lines.

  ➢Each viewing window has colored vertical and horizontal lines called cut-plane lines. The lines represent the location of the other two slices shown in MPR view.

  ➢For example, in the **Sagittal** view shown below:

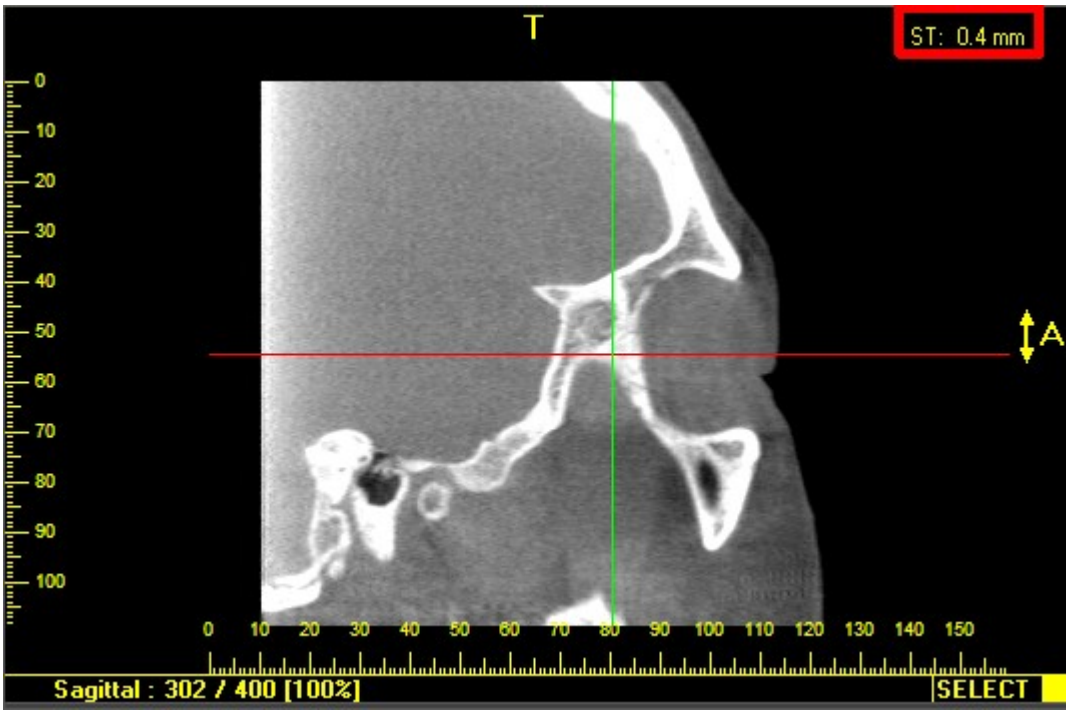
  - The green line represents the **Coronal** slice plane.
  - The red line represents the **Axial** slice plane.



- Cut-plane lines can be moved by clicking and dragging. This causes the images in the other view windows to change.
- Two cut-plane lines may be moved together simultaneously by grabbing the lines at their intersection.

Slice Thickness

The slice thickness is displayed in the upper right corner of each image in MPR view, in a box labeled ST.



Slice thickness can be changed by clicking on the **ST** box and selecting from the list.

- Min. ST for Sinus: 0.4 mm
- Min. ST for Temporal Bone: 0.2 mm

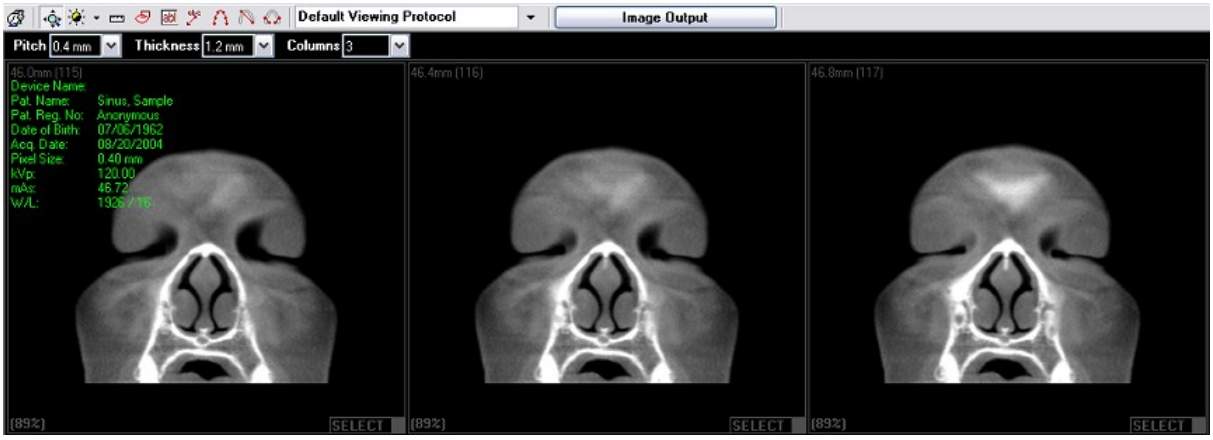
Pitch

Pitch is the distance between slices (also called the inter-slice distance or the slice gap). The pitch is only relevant in **Axial**, **Coronal**, or **Sagittal** views. To change the pitch, click on the down arrow and select a new value from the list.

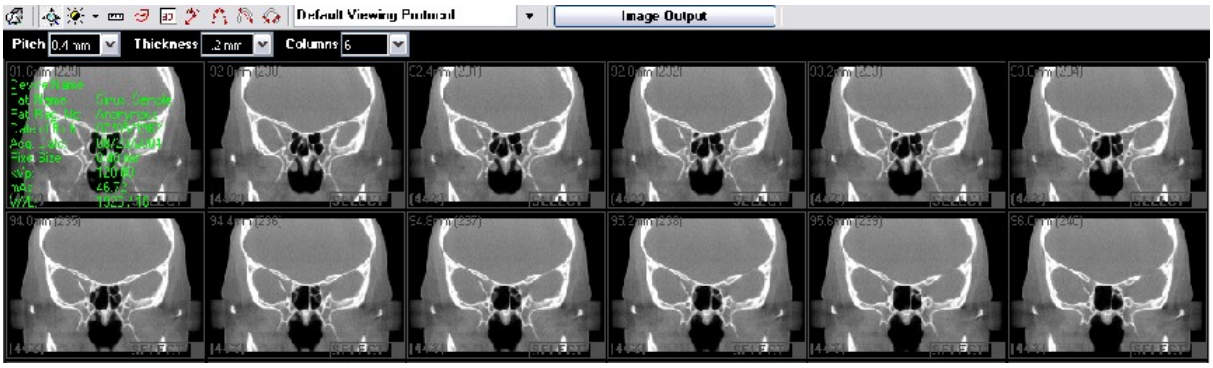
Columns

The number of slice images displayed on the screen in **Axial**, **Coronal,** or **Sagittal** views can be altered using the **Columns** pull-down menu. The following examples show 3 columns (top) versus 6 columns (bottom) in **Coronal** view.

- 3 columns:



- 6 columns:



Window / Level

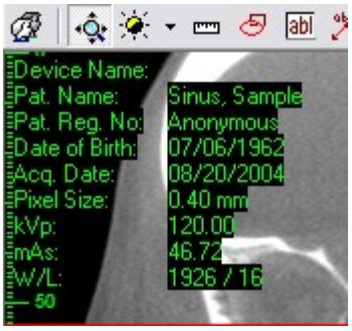
The **Window / Level** values determine the brightness and contrast of the displayed image. To adjust:

1. Click on the **Window / Level** icon in the toolbar:
2. The cursor will change to show that you are using the **W/L** tool. Now click and drag anywhere in the image.
    - Window value increases as the mouse is moved to the left of the image, and decreases

to the right.

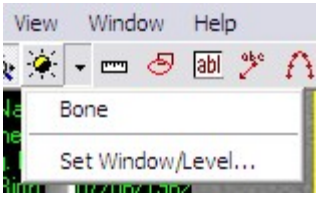
- Level value increases as the mouse is moved towards the top of the image, and decrease towards the bottom.

3. The Window / Level values appear in the patient information overlay, labeled **W/L**.



4. Preset options for W/L can be applied. Click on the down-arrow next to the brightness/contrast icon, and a drop-down menu will appear.

- Select **Bone** to restore the window and level values to their default values.

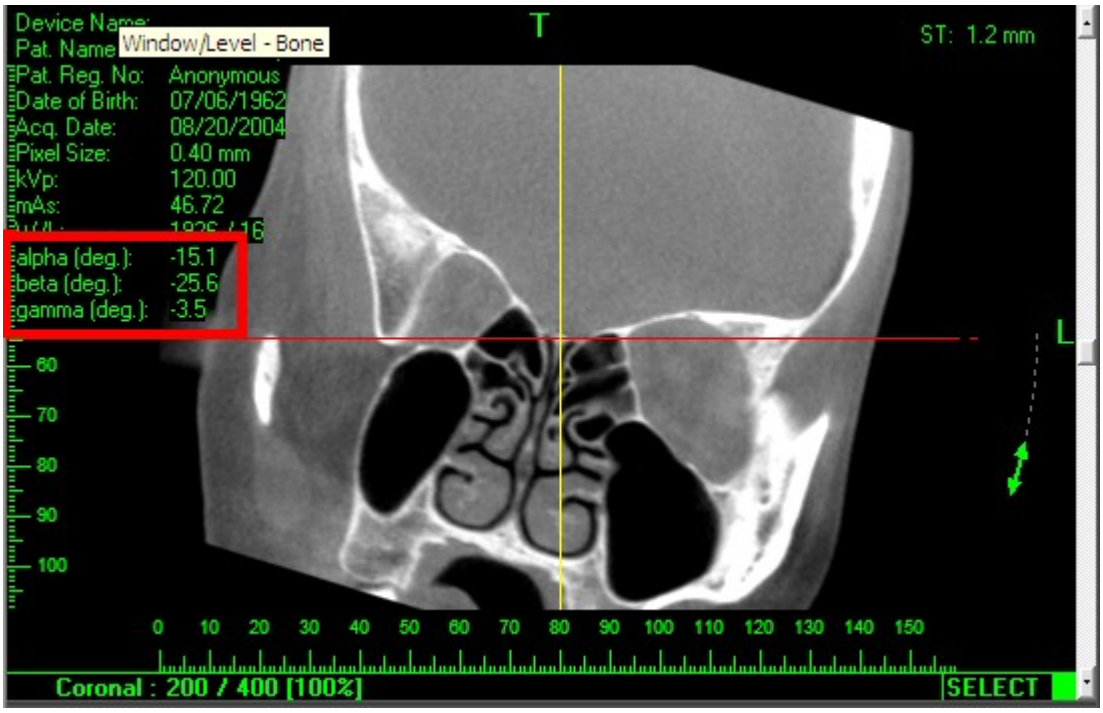


- Select **Set Window/Level** to manually adjust the window and level values for an image and save adjusted values as a new preset.

Rotate

The **Rotate** tool allows images to be rotated in **MPR** view.

- Find the double-ended arrow on the right side of the image.
- Click and drag the arrow up and down to rotate the image.
- Rotation angle adjustments are recorded in the patient information overlay, listed as **alpha**, **delta** and **gamma** angles (values in degrees).



- Images can be restored to their original non-rotated orientations by selecting the **Restore Original Tilt** option from the **View** menu.

7.5 Annotation Tools

The tools below allow you to make distance measurements and create comment overlays on images.

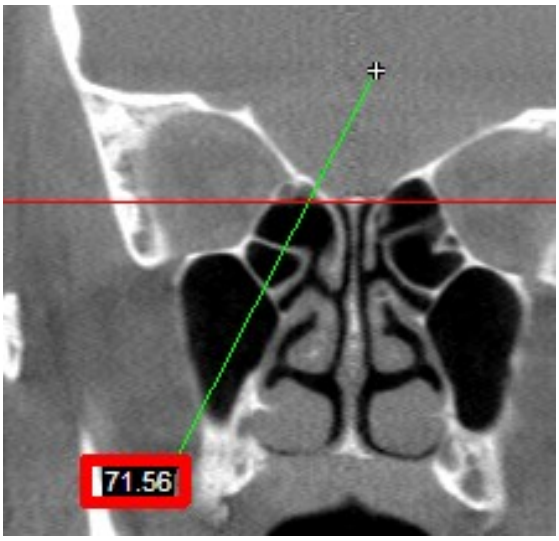
Note: All measurement and annotation tools can be used in any window where images are displayed.

Line Tool

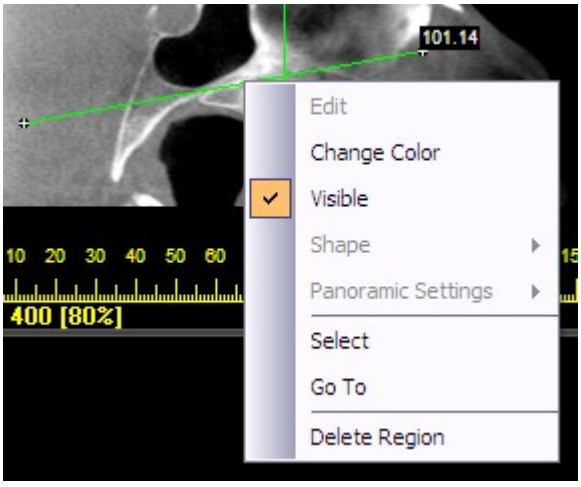
Using the **Line Tool**, measurements can be made between two points on an image (in millimeters).

1. Click on the **Line Tool** icon in the toolbar to activate the tool. (Looks like a ruler)
2. Left-click on the starting point of your desired measurement.
   Note: Click once on each endpoint. Do not hold mouse button down.
3. Move the cursor to the end point of your desired measurement and left-click. A distance

value will appear.
Note: The distance units are mm.



- Line objects can be moved by left-clicking the line and dragging it to the desired location.
- Line objects can be modified by right-clicking the line. A drop-down menu will appear with the following options:



Line Options	Description
Change Color	Changes the line color.
Visible	De-selecting this option makes the line disappear from view.

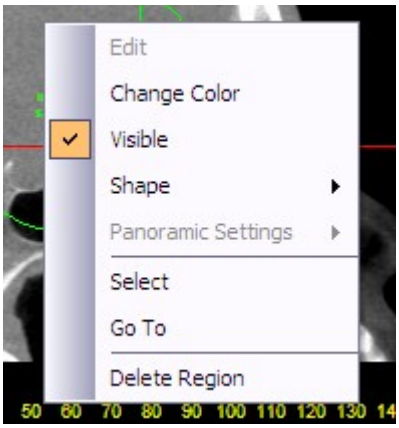
Line Options	Description
Select	This makes the line active (when other lines or objects are available).
Go To	This allows you to move back to the *MPR* view (from the *Oblique* or *TMJ* windows, for example).
Delete Region	This deletes the line object.

Shape Tool

The **Shape Tool** allows a region of any image to be selected and reports statistics of the image region within the shape outline.

1. Click on the **Shape Tool** icon in the toolbar to activate the tool.
2. Left-click on the center of the target region.
   Note: Click once. Do not hold mouse button down.
3. Left-click again on the edge of the target region, and a shape object will appear. Mean and standard deviation values will appear inside the ellipse.
   Note: The units of these values are in Hounsfield units.

- Shape objects can be moved by left-clicking the line and dragging it to the desired location.
- Shape objects can be modified by right-clicking the line. A drop-down menu will appear with the following options:



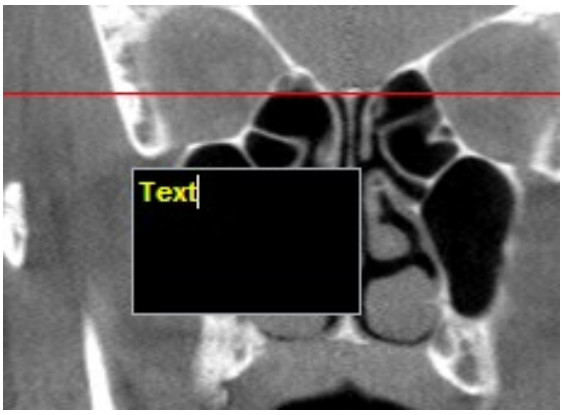
Shape Options	Description
Change Color	This changes the color of the shape.
Visible	De-selecting this option makes the shape disappear from view.
Shape	This changes the shape from an ellipse to a rectangle.
Select	This makes the ellipse active (when other objects are available).
Go To	This allows you to go back to the *MPR* view (from the *Oblique* or *TMJ* windows, for example).
Delete Region	This deletes the shape object.

Text Tool

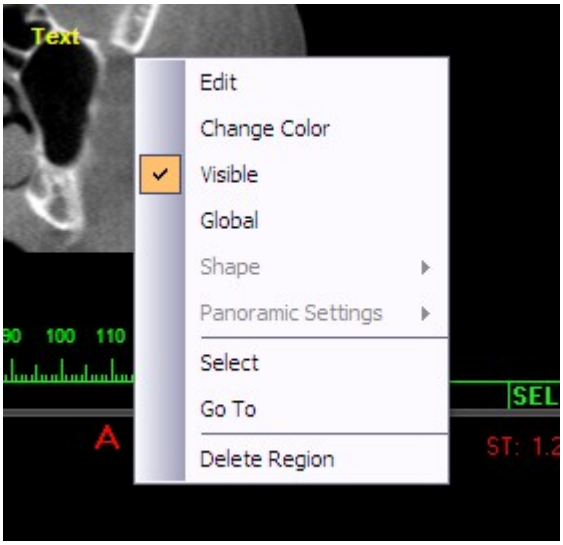
Text can be added to an image. This simple but flexible tool can be useful for labeling anatomical features, or making notes.

1. Click on the **Text Tool** icon from the toolbar.

2. Left-click and drag the cursor diagonally on an area of the image where the text box should be. Click again to release. Double-click on the word **Text**, and you can begin typing.



- Text objects can be moved by left-clicking the line and dragging it to the desired location.
- Text objects can be modified by right-clicking the line. A drop-down menu will appear with the following options:



Text Options	Description
Edit	Text can be edited.
Change Color	Text color to be changed.
Visible	De-selecting this option makes the text object disappear from view.

Text Options	Description
Global	Text will be visible on all the other slices in the dataset (within the same viewing window).
Select	Makes the text box active (when other objects are available).
Go To	Changes view to the *MPR* view (from *Oblique* or *TMJ* windows, for example).
Delete Region	Deletes the text box object.

Arrow Tool

Similar to the Text tool, but with an arrow to indicate a specific location on the image. Click on the **Arrow Tool** icon to enable this tool.

7.6 Oblique and TMJ Tools

The following are specialized tools for working with images.

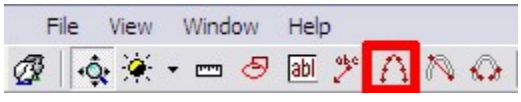
Oblique Tool

Two Points Oblique Tool

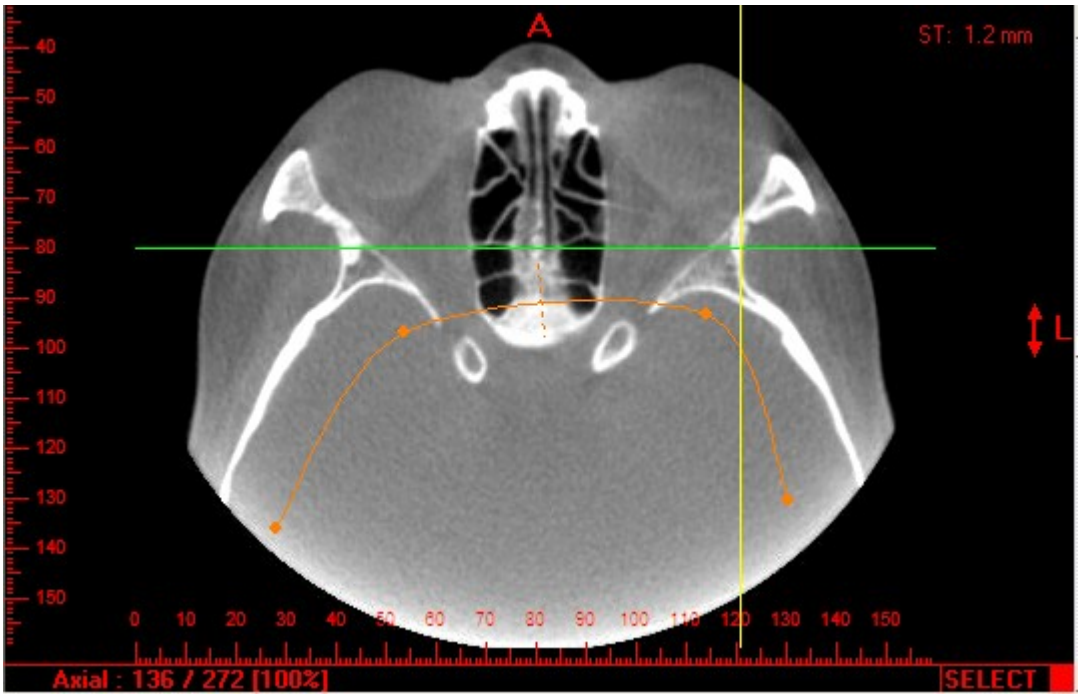
TMJ Tool

Oblique Tool

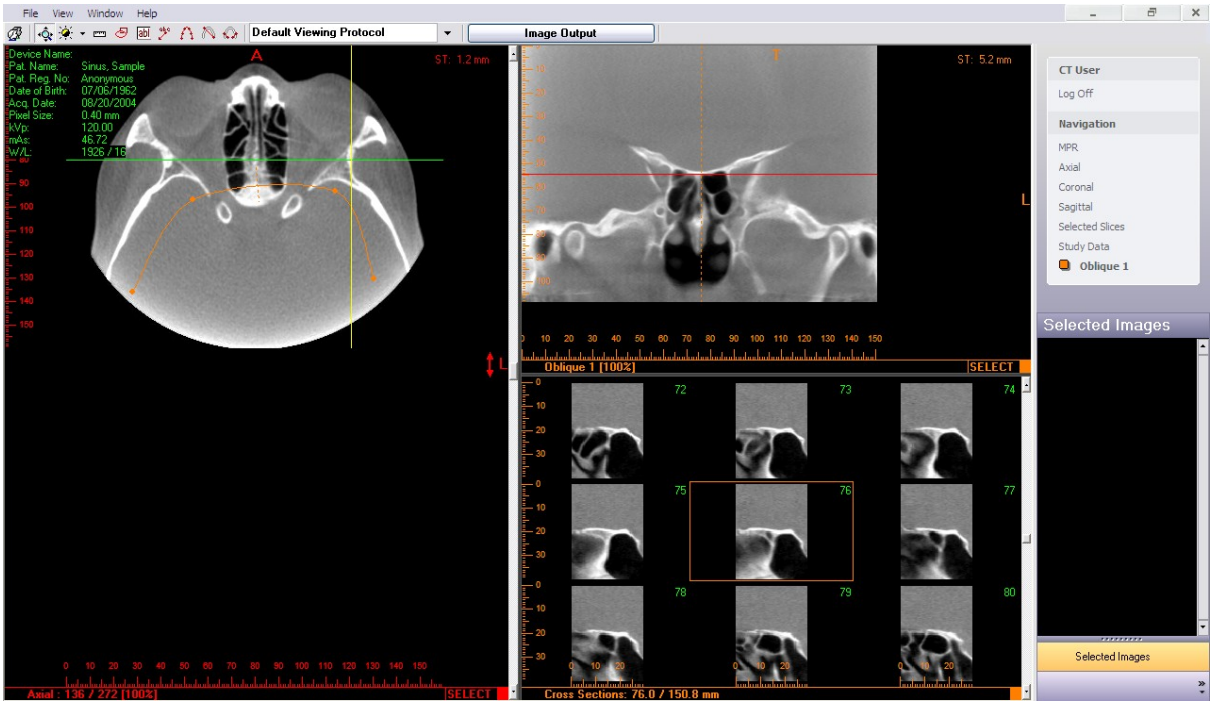
1. Click on the **Oblique** icon (outlined below in red). When this icon is active, you have the ability to flatten oblique and curved objects into a two-dimensional view.



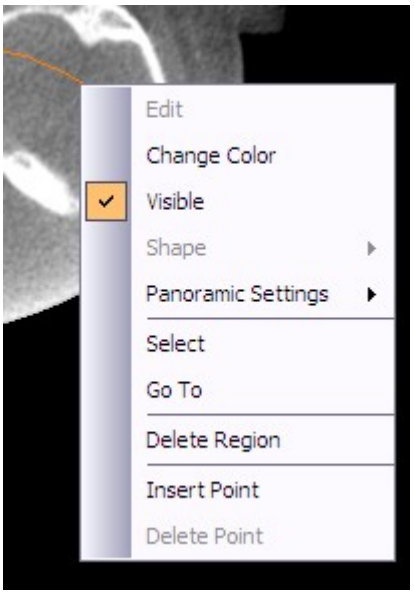
2. Left-click to deposit points along the desired pathway and double click on the last point to end the line. An example is shown below (an orange line with orange dots representing the points).



3. The following screen will appear:



- A new entry appears in the Navigation menu as "Oblique 1". You can toggle between this view and others by selecting the desired view in the Navigation menu (top right corner).
- The image on the left side shows the oblique pathway.
- The image at the top right shows the cut along the oblique pathway.
- The slice thickness is 0.4 mm and can be changed by left-clicking on the Slice Thickness (ST) value in the top right corner of the image and selecting a new value.
- The thumbnail images in the bottom right frame are cuts that are perpendicular to the oblique pathway. These are equally spaced along the length of the oblique pathway.
- You can move the oblique line by hovering over it with the cursor until it is active (it will change color), grabbing it by holding down the left mouse button and dragging it to the desired location.
- You can make changes to the oblique line by moving the cursor over it until the oblique line changes color and then right-clicking the mouse. A drop-down menu will appear with options. You can make similar changes by right-clicking the corresponding oblique line in the Navigation menu and choosing from the menu options.

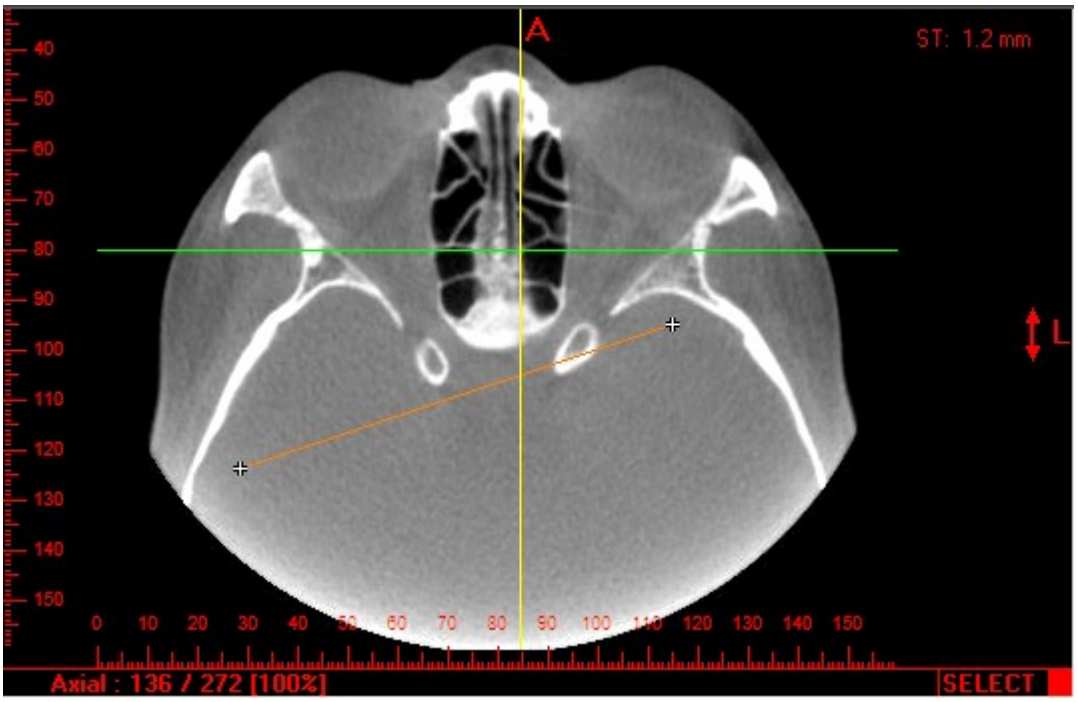


Oblique Options	Description
Change Color	This changes the Oblique line color.
Visible	This makes the oblique line invisible. In order to make the oblique line reappear, right click on the corresponding oblique line defined in the Navigation menu and select **Visible**.
Panoramic Settings	This allows you to change the resolution of the oblique images.
Select	This makes the oblique line active (when other oblique lines or objects are available).
Go To	Selecting this takes you to the *Oblique* window (the new screen that appears after you define an oblique line).
Delete Region	This deletes the oblique line.
Insert Point	This inserts an additional point.

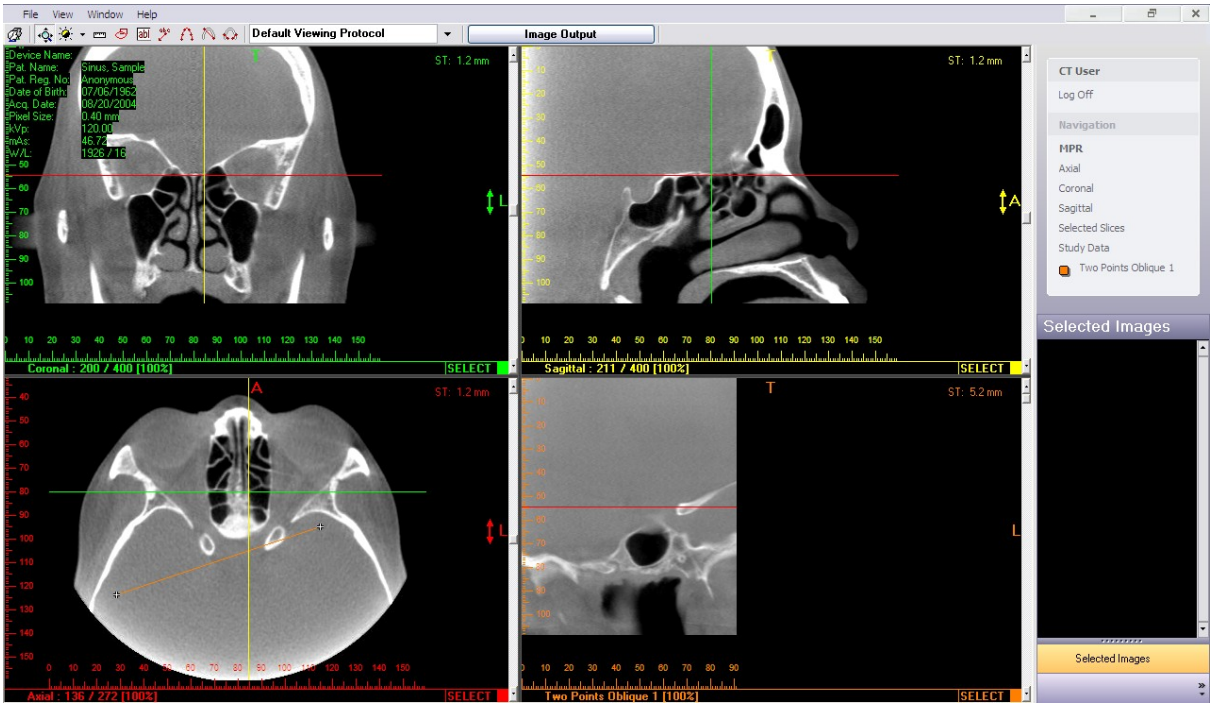
Two Points Oblique Tool

1. Click on the **Two Points Oblique** icon (outlined below in red). When this icon is active, you have the ability to flatten oblique and curved objects into a two-dimensional view.

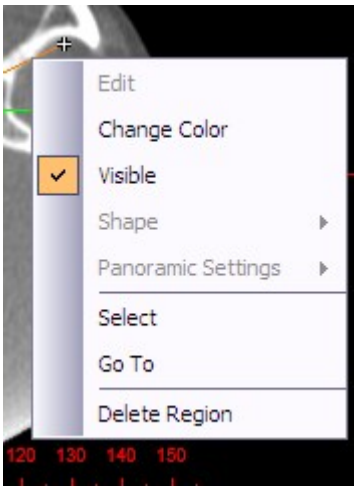
2. Left-click to deposit two points along the desired pathway. An example is shown below (an orange line with orange dots representing the click points).



3. The following screen will appear:



- A new entry appears in the Navigation menu as "Two Points Oblique 1". You can toggle between this view and others by selecting the desired view in the Navigation menu (top right corner).
- The image on the left side shows the oblique pathway.
- The image on the lower right shows the cut along the oblique pathway.
- The slice thickness is 0.4 mm and can be changed by left-clicking on the Slice Thickness (ST) value in the top right corner of the image and selecting a new value.
- You can move the oblique line by hovering over it with the cursor until it is active (it will change color), grabbing it by holding down the left mouse button, and dragging it to the desired location.
- You can make changes to the oblique line by moving the cursor over it until the oblique line changes color and then right-clicking the mouse. A drop-down menu will appear with options. You can make similar changes by right-clicking the corresponding oblique line in the Navigation menu and choosing from the menu options.

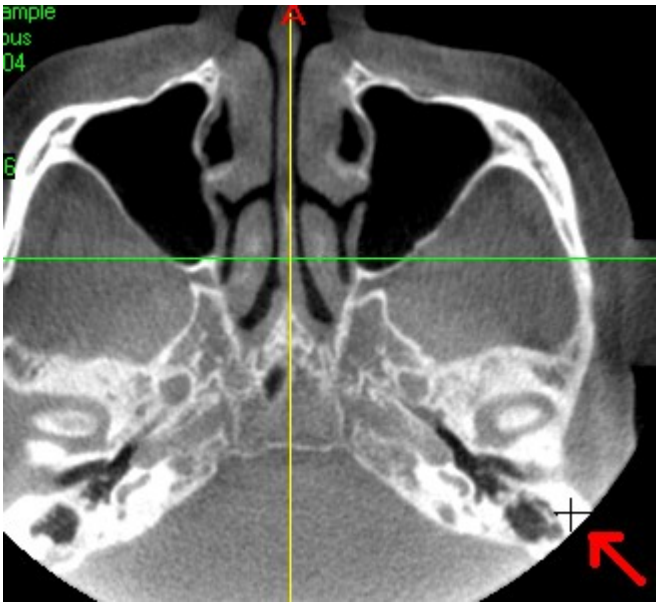


Two Points Oblique Options	Description
Change Color	This changes the oblique line color.
Visible	This makes the oblique line invisible. To make the oblique line reappear, right click the corresponding oblique line defined in the Navigation menu and select "Visible".
Select	This makes the oblique line active (when other oblique lines or objects are available).
Go To	Selecting this takes you to the *Oblique* window (the screen that appears after you define an oblique line).
Delete Region	This deletes the oblique line.

TMJ Tool

1. Click on the **TMJ** icon (outlined below in red). When this icon is active, you have the ability to look at the temporal mandibular joints in a two-dimensional view.

2. Left-click below and to the right of the patient's left condyle (this is a radiological view, so patient's left is the right side of the image). Alternatively, you could choose a point below and to the left of the patient's right condyle. The point chosen for this example is highlighted with the red arrow.



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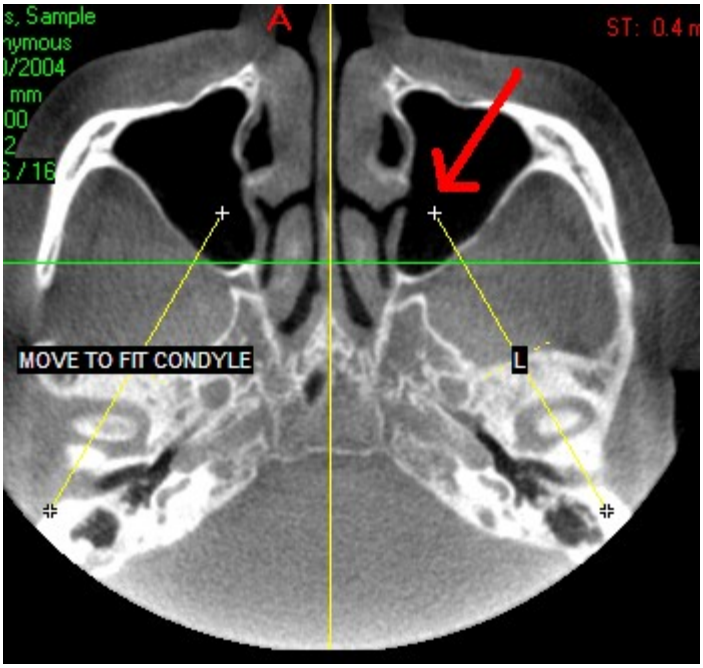
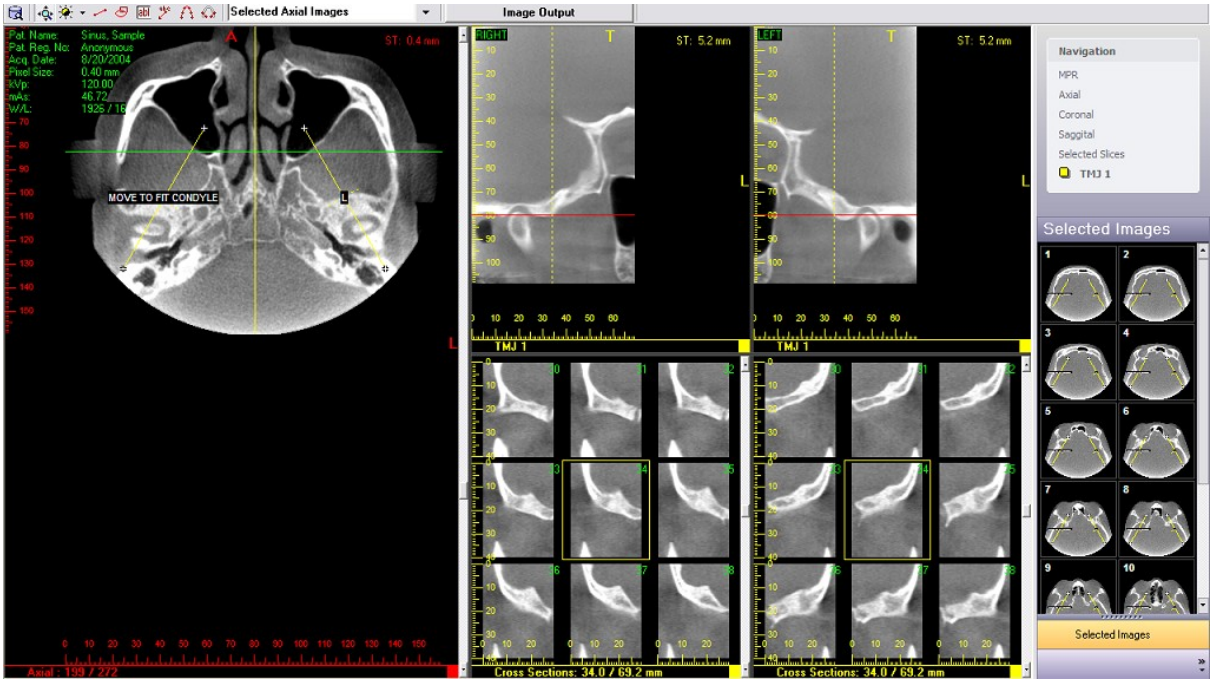
3. Move the cursor up and to the left (patient's right) to deposit the second point. The line that connects these two points should cross over the center of the joint. The second point chosen for this example is highlighted with the red arrow.

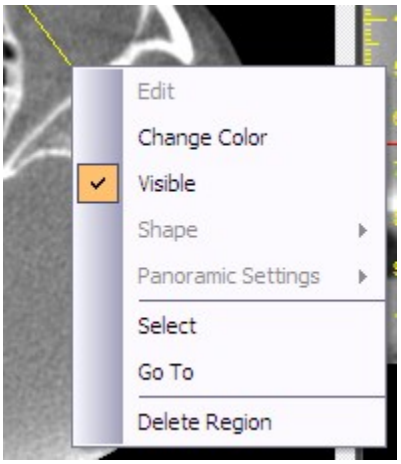
   As soon as this point is selected, the letter "L" appears over this line, indicating the patient's left. A second line appears on the patient's right side that may or may not be over the right condyle. You can move this line so that it is positioned properly.



4. Double click on the second point and the following screen will appear:



- A new entry appears in the Navigation menu as "TMJ 1". You can toggle between this view and others by selecting the desired view in the Navigation menu (top right corner).
- The two images in the upper right portion of the screen are the right and left image cuts along the TMJ lines.
- The slice thickness is 5.2 mm and can be changed by left-clicking on the Slice Thickness (ST) value in the top right corner of each image and selecting a new value.
- The two panes of small images are cuts that are perpendicular to the TMJ lines. These are equally spaced along the length of each TMJ line.
- You can move the TMJ lines by hovering over them with the cursor until they are active (they will change color), grabbing them by holding down the left mouse button, and dragging them to the desired location.
- You can make changes to the TMJ lines by moving the cursor over them until the TMJ lines change color and then right-clicking with the mouse. A drop-down menu will appear with options. You can also make similar changes by right-clicking the corresponding TMJ lines in the Navigation menu and choosing from the following menu options:



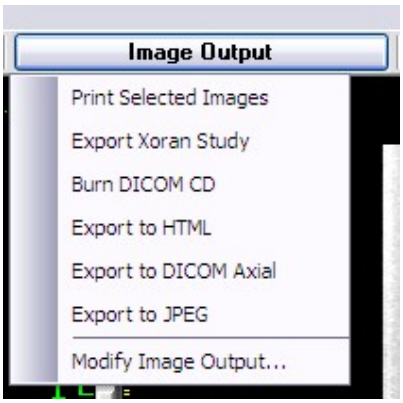
TMJ Options	Description
Change Color	This changes the TMJ line color.
Visible	This makes the TMJ lines invisible. To make the TMJ lines reappear, right click on the corresponding TMJ lines defined in the Navigation menu and select "Visible".
Select	This makes the TMJ lines active (when other TMJ lines or objects are available).
Go To	Selecting this takes you to the *TMJ* window (the screen that appears after you define a pair of TMJ lines).
Delete Region	This deletes the pair of TMJ lines.

8.0 OUTPUT IMAGES

MiniCAT™ makes an image output easy with preset protocols for printing, burning to CD/USB drive and transferring images over a network.

1. If printing, ensure that the desired slices appear under **Selected Slices** view.

2. Click the **Image Output** menu (along the main toolbar of the screen) to view all output protocols.



3. Left-click on the desired image output protocol. They are described below.

Output Protocol	Description
Print Selected Images	This option automatically prints the images in the *Selected Images* window. The default image layout is 3 rows by 2 columns.
Export Xoran Study	This exports Xoran study data to either a CD or USB flash drive.
Burn DICOM CD	This burns a Xoran image data onto a CD in DICOM format, which is compatible with most IGS systems.
Export to HTML	This exports a Xoran study in HTML format, viewable on any computer with a browser such as Internet Explorer.
Export to DICOM Axial	This exports the axial slices of a Xoran study onto a CD in DICOM format.
Export to JPEG	This exports a Xoran study in JPEG picture format.
Modify Image Output	Image output protocols can be modified. Xoran support is available to assist with creating custom output protocols.

Output Protocol	Description
DICOM Push	Allows a study to be uploaded to a DICOM server such as a PACS system. Call Xoran customer support to help set this up. (We will need to contact your local IT person)

9.0 TECHNICAL SPECIFICATIONS

9.1 General Information

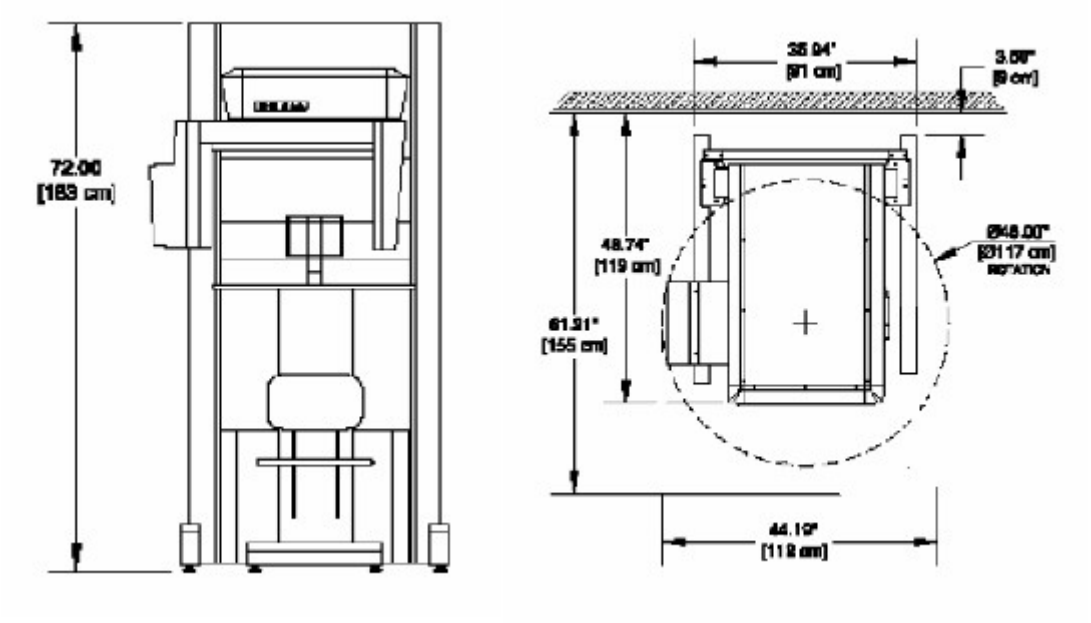
MiniCAT Scanner

System Description	MiniCAT™ is a volume tomography X-ray machine for medical applications. The system has been designed for low radiation dose imaging of the sinuses, skull base and temporal bone.
System Dimensions	46" x 49" x 72" tall (117 x 119 x 183 cm) 46" x 49" x 67" effective August 2007 (117 x 119 x 170 cm)
Minimum Room Size	6' x 9'
Weight	450 lbs
Internet Connectivity	High speed connection is required for service/ maintenance.

Patient Support Chair

Overall Dimensions	30.5"d x 29”w x 50.5”h (77.5 cm x 73.7 cm x 128.3 cm)
Weight	115 lbs (52 kg)
Seat Height Adjustment	12.5” to 21.5 (31.8 cm to 54.6 cm)
Maximum Patient Weight	350 lbs (159 kg)

FRONT VIEW **TOP VIEW**



9.2 Imaging Properties

Imaging Properties	
Detector Data Channels	758
Detector Element Size	254 µm x 254 µm

Reconstructed Voxel Size	0.2 mm minimum
Reconstruction Time	~60 sec for 200 slices
Field of View, Axial	12 cm max
Field of View, Cross-sectional	16.5 cm max
Views	MPR/Axial/Coronal/Sagittal/ Panoramic cross-section/ Raw data cine
Gray Scale Display	256 levels
Display Window	Adjustable level and width
Gantry Rotation Angle	360º
Workstation	Intel-based PC
Compatibility	DICOM 3.0

Standard Imaging Protocols

Imaging Protocol	Scan Time	Axial Slices	Coronal Slices	Sagittal Slices	kVp	mA	mAs	Effective Dose	Slice Thickness	Voxel Size
Adult Sinus	40 s	272	400	400	120	5	68	0.13 mSv	0.4 mm	0.4 mm
Pediatric Sinus	20 s	272	400	400	120	5	34	0.07 mSv	0.4 mm	0.4 mm
Follow-up Sinus	10 s	272	400	400	120	5	17	0.04 mSv	0.4 mm	0.4 mm
Temporal Bone	40 s	228	600	600	125	7	76	0.14 mSv	0.3 mm	0.3 mm

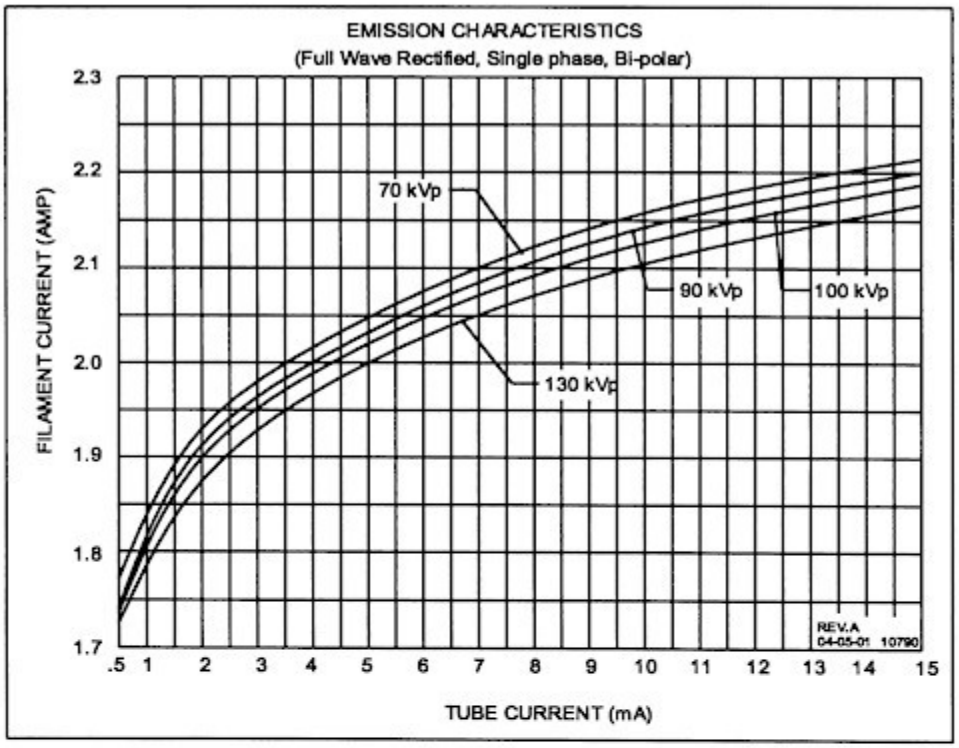
9.3 X-Ray Specifications

X-Ray Specs

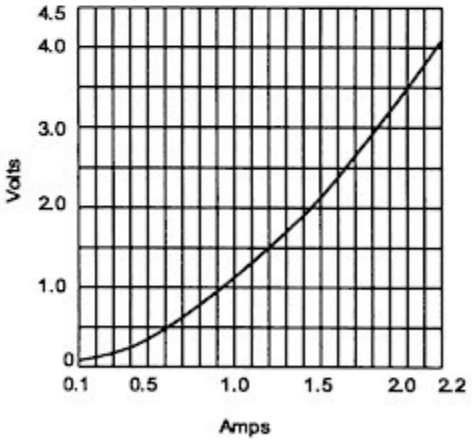
X-Ray Tube Head Assembly

Manufacturer	Imaging Sciences International, Hatfield PA USA
Generator	High frequency, constant potential
Rating	125 kVp, 3-8 mA
Nominal Electric Power	1 kW
Total Filtration (at 120 kVp)	Nominal filtration 10 mm Al equivalent. Additional filtration <= 3 mm Al equivalent.
Exposure	16-80 mAs
Scattered Radiation at 3’	<0.7 mR
Model Number	See tube head
Serial Number	See tube head

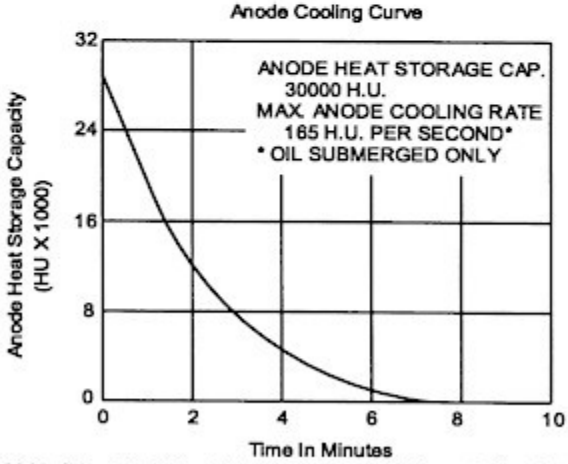
X-Ray Tube	
Manufacturer	Superior X-Ray, Woodstock, IL USA
Model Number	SXR-130-15-0.5
Tube Type	Stationary anode
Max. Tube Voltage	130 kVp (full wave rectified) *
Max. Tube Current	8 mA
Max. Power	1.04 kW
Target Material	Tungsten
Target Angle	15 degrees
Focal Spot Size	~0.5 mm
* Actual tube voltage and current can be measured. See MiniCAT™ Installation Guide.	



Filament Volt/Amps Characteristics:
60 Hz AC & DC



Anode Cooling Curve



H.U. (Heat Units) = kVp (Kilovolts Peak) x mA (rms) x Time (sec.)
Joules = .707 x H.U.

SUPERIOR X-RAY TUBE CO.
06-29-04

SXR-130-15-0.5
0.5 FOCAL SPOT

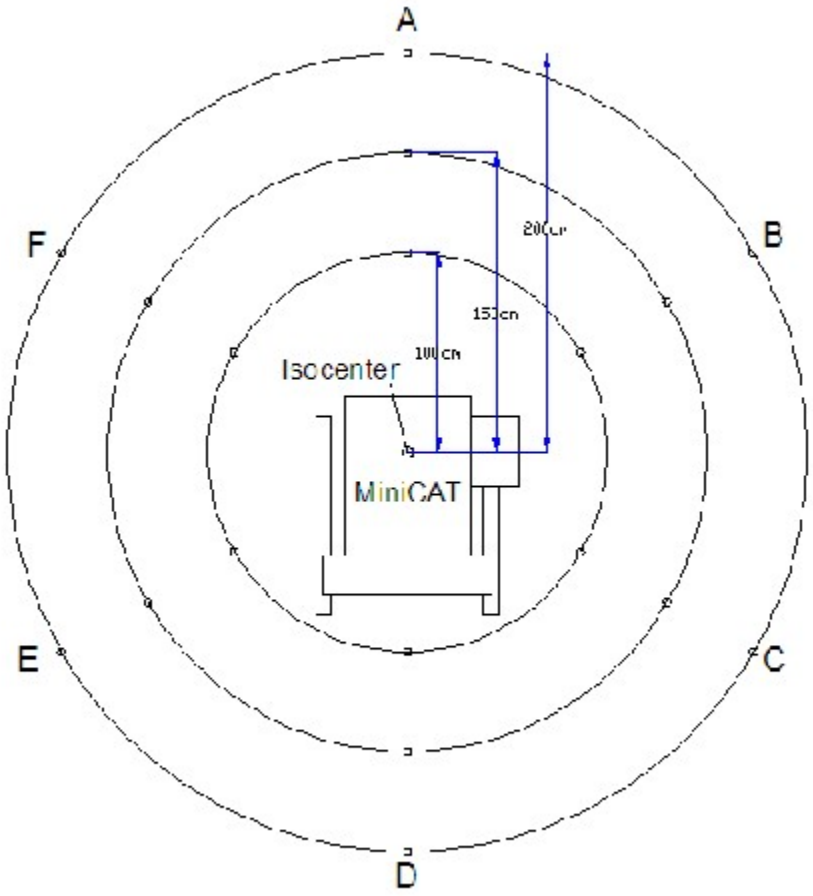
9.4 Scatter Map

Scatter Map

Xoran Technologies® MiniCAT™

Secondary Radiation Measurements

Secondary scatter radiation was measured on the MiniCAT™ using optically stimulated luminescence (OSL) dosimeters provided and processed by Landauer®. The measurements were taken at the 6 azimuthal locations A through F and at radii 1.0, 1.5, and 2.0 meters from isocenter and in the same plane as the central slice (i.e. level with the focal spot) which was approximately 120 centimeters above the floor.



The MiniCAT™ was operated at 120 kVp and 57 mAs per 40 second scan for all secondary radiation measurements reported.

The secondary radiation dose was recorded by the OSL dosimeters for 200 scans and read out by Landauer®. The OSL dosimeters have a minimum reporting dose of 1 millirad. The reported dose for each OSL dosimeter was divided by the number of scans and reported in the following table.

Secondary Dose Measurements Per Scan Level with Central Slice		
Azimuthal Location	**Radius (meter)**	**Dose Per Scan (millirad)**
A	1.0	0.94
	1.5	0.47
	2.0	0.28
B	1.0	0.99
	1.5	0.45
	2.0	0.28
C	1.0	1.13
	1.5	0.52
	2.0	0.28
D	1.0	1.18
	1.5	0.47
	2.0	0.28
E	1.0	1.17
	1.5	0.52
	2.0	0.29
F	1.0	0.87

Secondary Dose Measurements Per Scan Level with Central Slice		
Azimuthal Location	**Radius (meter)**	**Dose Per Scan (millirad)**
	1.5	0.40
	2.0	0.28

The secondary radiation doses were also recorded at 0.5 meters above and 0.5 meters below the horizontal plane intersection the central slice at azimuthal locations A through F and at a radius of 1.0 meter. These measurements are reported in the following tables.

Secondary dose measurements per scan 0.5 meters below central slice at radius of 1 meter	
Azimuthal Location	**Dose Per Scan (millirad)**
A	1.15
B	1.00
C	1.05
D	0.90
E	0.98
F	1.01

Secondary dose measurements per scan 0.5 meters above central slice at radius of 1 meter	
Azimuthal Location	**Dose Per Scan (millirad)**
A	0.64
B	0.75
C	0.81

Secondary dose measurements per scan 0.5 meters above central slice at radius of 1 meter	
Azimuthal Location	**Dose Per Scan (millirad)**
D	0.03
E	0.84
F	1.89

9.5 Dose Information

CTDI Dose Measurements

The following dose measurements were made on a MiniCAT™ using a PMMA head phantom with a diameter of 16 centimeters and a 10 cc ion chamber with an active length of 10 centimeters. The peripheral location was chosen to be the maximum CTDI100 obtainable at that depth. The conditions of operation and the resulting CTDI measurements are representative of the MiniCAT™ volume CT scanner and could vary for measurements made on a particular unit.

Protocol	**kVp**	**mA**	**mAs**	**Scan Time (seconds)**	**Number of Projections**	**Beam Width at Isocenter (mm)**	**$CTDI_{100,center}$ (mGy)**	**$CTDI_{100,peripheral}$ (mGy)**	**$CTDI_{w}$ (mGy)**	**$CTDI_{vol}$ (mGy)**
Sinus 40s	120	5	45	40	602	133	3.74	3.57	3.57	3.57
Sinus 20s	120	5	22	20	302	133	1.86	1.72	1.77	1.77
Sinus 10s	120	5	11	10	152	133	0.93	0.86	0.89	0.89
Temporal Bone	125	7	63	40	602	105	9.60	8.78	9.05	9.05

The conventional definition of CTDI100 was modified slightly to account for the large cone angle and resulting beam width associated with the flat-panel detector CT geometry. The dose was integrated over the active length of the detector along a line perpendicular to the tomographic plane and divided by the width of the X-ray beam at isocenter (BW).

$$CTDI_{100} = \int_{-50\,mm}^{50\,mm} \frac{D(z)}{BW} dz$$

Once the $CTDI_{100}$ was calculated for the center and peripheral location, the $CTDI_w$ was calculated according to the following equation:

$$CTDI_w = \frac{1}{3} CTDI_{100,center} + \frac{2}{3} CTDI_{100,peripheral}$$

The MiniCAT™ acquires data in one axial rotation and reconstructs into a volume of data without any motion in the z-direction (i.e. helical or incremental scanning). Therefore, the $CTDI_{vol}$ is equal to the $CTDI_w$.

9.6 Installation Requirements

Installation Requirements

Room Requirements	
Minimum Room Size	6' x 9'
Internet Connectivity	High speed connection is required for service/maintenance.
Note: Room layout must be such that operator of equipment is able to make visual and audio contact with patient being scanned while operating the equipment from behind operator's barrier.	

Electrical Power Requirements			
	Japan	**Europe**	**USA**
Line Voltage*	~100 V	~220-240 V	~115 V
Line Frequency	50 - 60 Hz	50 - 60 Hz	50 - 60 Hz
Line Current	5 A Standby	2.5 A Standby	5 A Standby
Main Circuit Breaker	10 A Max.	5 A Max.	10 A Max.
* Voltage must be held to within +- 10% of specified Line Voltage.			

Environmental Conditions

It is recommended that MiniCAT™ is operated in a climate-controlled clinical or hospital environment. Changes in temperature may cause the system to require additional calibration.

Operating Requirements	50 to 95 degrees Fahrenheit (10 to 40 degrees Celsius) 45% to 75% humidity
Transportation and Storage Requirements	32 to 104 degrees Fahrenheit (0 to 40 degrees Celsius) 30% to 80% humidity
Heat Dissipation	Approx. 500W / 1700 BTU/hr

Caution: Allow system temperature to adapt to room temperature before powering up MiniCAT™ scanner hardware or workstation/server.

Installation/Relocation

MiniCAT™ can not be installed or relocated by the user. Proper and safe setup requires specialized training and must be performed by a Xoran Technologies Customer Service Engineer. Call Xoran 1-800-70-XORAN (800-709-6726) for assistance.

Apparent Resistance of Supply Mains

For the purpose of obtaining the apparent resistance of supply mains on the MiniCAT™ CT system model# 010000-03, resistance is determined according to the following formula

$$R = \frac{U_0 - U_1}{I_1}$$

Where:

U_0 is the no-load MAINS VOLTAGE.
U_1 is the MAINS VOLTAGE under load.
I_1 is the mains current under load.

MiniCAT™ CT system utilize single-phase power. Measurements were performed between phase and neutral. Measured results:

Apparent Resistance of Supply Mains
U_0 = 121.1V AC U_1 = 120.7V AC I_1 = 8.3A
Result: Apparent Resistance of Supply Mains (R) = 0.048ohms

9.7 IGS Compatibility

IGS Compatibility

The following tables summarize the compatibility of MiniCAT™ with other image guided systems.

GE	
Platform	**Compatible with Xoran**
IT3500+, ENTrak+, ConneCTstat+	Yes
IT3500, ENTrak, ConneCTstat	No
IT3000	No
IT2000	No

Medtronic/LandmarX/Xomed	
Platform	**Compatible with Xoran**
LandmarX Evolution, LandmarX Evolution Plus, LandmarX Element	Yes
LandmarX gen1, LandmarX gen2	No
Medtronic Stealth, Treon, Ion, Tria	No
Medtronic Treon Plus (w/ ENT software), Tria Plus (w/ ENT software)	Yes

BrainLAB (Requires Pac Xfer Version 5.2 or Higher)	
Platform	**Compatible with Xoran**
VectorVision	Yes
VectorVision2	Yes
VectorVision Compact (for ENT)	Yes
Kolibri	Yes

Stryker	
Platform	**Compatible with Xoran**
Stryker Navigation System (original)	Yes
NavII	Yes
mNAV	Yes

10.0 QUALITY CONTROL TESTS

Overview

Xoran encourages MiniCAT™ owners to develop a quality assurance program with the assistance of a qualified medical physicist. In this section, we recommend some tests which can be included in the program. Xoran recommends that these tests be performed and interpreted by a qualified medical physicist or a state-authorized service technician in accordance with local regulations.

Xoran recommends that quality control tests be performed once a year and as regularly as required by state radiation safety regulations. MiniCAT™ owners participating in a MiniCAT™ service agreement are eligible to receive assistance performing these test procedures from Xoran Customer Service personnel. However, Xoran recommends (and your state may require) that a medical physicist performs an independent evaluation. Xoran provides a quality control phantom to use for these quality control tests. Xoran also provides a QC Test Log Form as a template for recording these test procedures.

Xoran has developed these procedures based on the fact that the scanner is designed to scan only the sinuses and temporal bones, which are high-contrast or 'bone window' imaging tasks that require isotropic high spatial resolution and do not require the level of contrast resolution needed for other imaging tasks, such as brain or muscle tissue scanning, etc. Xoran designed the MiniCAT™ according to the ALARA (As Low As Reasonably Achievable) principle by minimizing the radiation dose to the patient while providing the image quality necessary for scanning the sinuses and temporal bones.

Should your MiniCAT™ system fail any of the following quality control tests, contact XORAN AT (800) 70-XORAN for corrective action.

10.1 CT Number Accuracy Test

CT Number Accuracy Test

Equipment: Cylindrical water phantom

Procedure:

1. Perform a scan of the cylindrical water phantom using the "Sinus" protocol.
2. Use the "Shape Region" tool from the toolbar to draw a circular region of interest of approximately 1 cm in diameter in the center of the phantom.
3. Read and record the mean value and standard deviation.

Tolerance: The mean CT number of water is expected to be 0±100 units, while the standard deviation is expected to be within 30±20 units.

10.2 CT Number Linearity Test

CT Number Linearity Test

Equipment: Quality control phantom

Procedure:

1. Perform a scan of the resolution phantom in "Resolution Protocol" scanning protocol.
2. Allow the MiniCAT™ software to reconstruct the image.
3. Use the "Shape Regions" tool to measure the average value within the four linearity inserts on an axial cut in the reconstructed image.
4. Calculate and record the correlation coefficient between the measured values and the expected values. The expected values are -1000, -100, 120, and 990. The calculation can be done in a spreadsheet application using a correlation coefficient function.

Tolerance: The correlation coefficient should be between 0.95 and 1.

10.3 Artifact Test

Artifact Test

Equipment: Cylindrical water phantom

Procedure:

1. Using the scan from the CT Number Accuracy test, scroll through all the axial slices and try to visually detect any potential image artifacts, such as rings from bad detector elements or non-uniformity artifacts.

Tolerance: The images should be free from artifacts.

10.4 Spatial Resolution Test

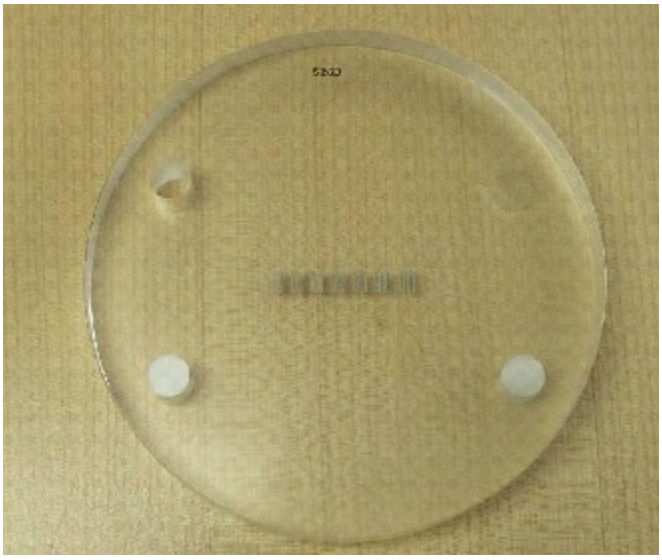
Spatial Resolution Test

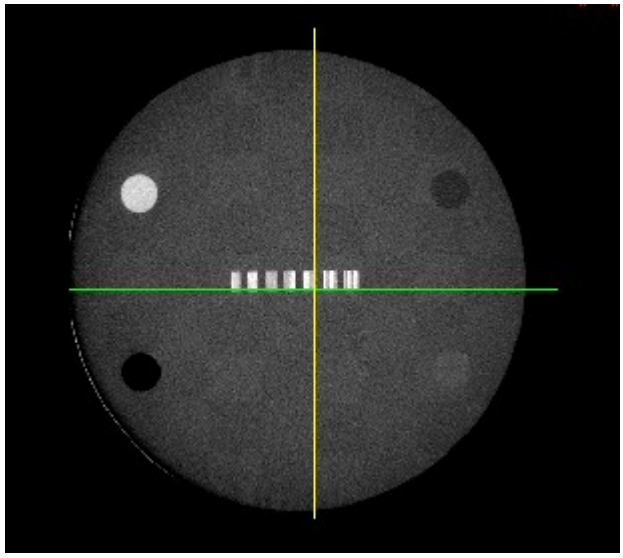
Equipment: Quality control phantom

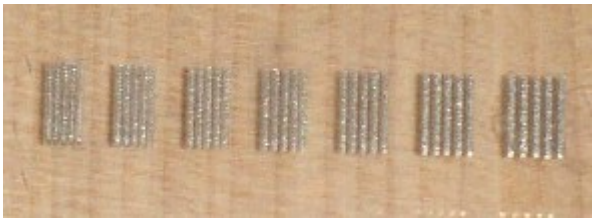
Procedure:

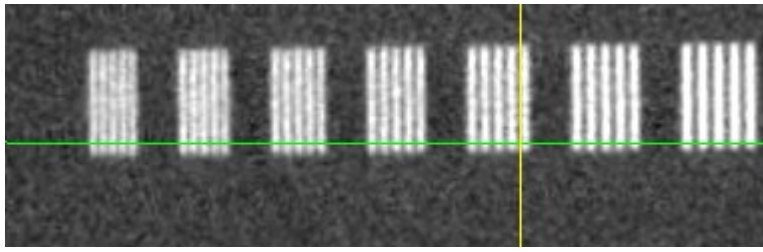
1. Use the reconstructed scan of the resolution phantom from the previous test.
2. Note the visibility of the highest frequency line pair pattern (15 lp/cm) on an axial slice in the reconstructed image.

Tolerance: The highest frequency line pair pattern of 15 lp/cm should be visible.









10.5 QC Test Log Form

MiniCAT™ Quality Control Test Log Form

Date: _____

Performed by: _____

1. CT Number Accuracy Test

Water Number: _____ (Should be 0±100 units)

Water STD: _____ (Should be 30±20 units)

2. Water Phantom Artifact Test

Circle one: Yes / No No ring artifacts should be visible.

3. CT Number Linearity Test

Linearity coefficient: _____ (Should be less than 1 and higher than 0.95)

4. Spatial Resolution Test

Highest visible line pairs per centimeter: _____ (Should be 15 lp/cm, the highest frequency pattern)

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